IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

| JOHN BATTAGLIA | § | |
|--------------------------------|--|-------------------------|
| Plaintiff, | \$ \$ \$ \$ \$ \$ | |
| | § | |
| $\mathbf{vs.}$ | § | CIVIL ACTION NO |
| | | |
| BRYAN COLLIER, | § | |
| Executive Director, | § | |
| Texas Department of Criminal | <i>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</i> | DEATH PENALTY CASE |
| Justice, | § | |
| | § | |
| LORIE DAVIS, | § | PLAINTIFF JOHN |
| Director, Correctional | § | BATTAGLIA IS SCHEDULED |
| Institutions Division, | § | FOR EXECUTION TODAY, |
| Texas Department of Criminal | § | FEBRUARY 1, 2018 |
| Justice, | § | |
| | § | |
| JAMES JONES, | § | |
| Senior Warden, Huntsville Unit | § | |
| Huntsville, Texas, | § | |
| | § | |
| and | § | |
| | § | |
| UNKNOWN EXECUTIONERS; | § | |
| Defendants. | § | |
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EXHIBITS TO PLAINTIFF'S REQUEST FOR A TEMPORARY RESTRAINING ORDER

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EXHIBIT A

TEXAS DEPARTMENT OF CRIMINAL JUSTICE

CORRECTIONAL INSTITUTIONS DIVISION



EXECUTION PROCEDURE

July 2012

ADOPTION OF EXECUTION PROCEDURE

In my duties as Division Director of the Correctional Institutions Division, I hereby adopt the attached Execution Procedure for use in the operation of the Texas Department of Criminal Justice Death Row housing units and perimeter functions. This Procedure is in compliance with Texas Board of Criminal Justice Rule §152.51; §§492.013(a), 493.004, Texas Government Code, and Article 43.14 – 43.20, Code of Criminal Procedure.

Director, Correctional Institutions Division

EXECUTION PROCEDURES

PROCEDURES

- I. Procedures Upon Notification of Execution Date
 - A. The clerk of the trial court pursuant to Tex Code of Criminal Procedure art. 43.15 shall officially notify the Correctional Institutions Division (CID) Director, who shall then notify the Death Row Unit Warden, and the Huntsville Unit Warden of an offender's execution date. Once an execution date is received, the Death Row Unit Warden's office shall notify the Unit Classification Chief, and the Death Row Supervisor.
 - B. The Death Row Supervisor shall schedule an interview with the condemned offender and provide him with the Notification of Execution Date (Form 1). This form provides the offender with a list of the information that shall be requested from him (2) two weeks prior to the scheduled execution.
 - C. The condemned offender may be moved to a designated cell. Any keep-on-person (KOP) medication shall be confiscated and administered to the offender as needed by Unit Health Services staff.

II. Stays of Execution

- A. Official notification of a stay of execution shall be delivered to the CID Director, the Death Row Unit Warden, and the Huntsville Unit Warden through the Huntsville Unit Warden's Office. Staff must not accept a stay of execution from the offender's attorney. After the official stay is received, the Death Row Unit Warden's office shall notify the Unit Classification Chief and Death Row Supervisor.
- B. Designated staff on the Death Row Unit shall notify the offender that a stay of execution has been received.
- III. Preparation of the Execution Summary and Packet
 - A. Two Weeks (14 days) Prior to the Execution
 - 1. The Death Row Unit shall begin preparation of the Execution Summary. The Execution Summary (Form 2) and the Religious Orientation Statement (Form 3) shall be forwarded to the Death Row Supervisor or Warden's designee for completion. A copy of the offender's current visitation list and recent commissary activity shall also be provided.

Execution Procedure

- 2. The Death Row Supervisor shall arrange an interview with the condemned offender to gather the information necessary to complete the Execution Summary and Religious Orientation Statement.
- 3. An offender may request to have his body donated to the Texas State Anatomical Board for medical education and research. The appropriate paperwork shall be supplied to the offender upon request.
- 4. The Execution Summary must be completed and returned by the Death Row Supervisor or Warden's designee in sufficient time to be forwarded to the CID Director's Office by noon of the 14th day. After approval by the CID Director, the summary shall be forwarded to the Death Row Unit Chaplain, the Huntsville Unit Warden's Office, and Public Information.
- 5. If the offender wishes to change the names of his witnesses, and it is less than fourteen (14) days prior to the scheduled execution, the offender shall submit a request in writing to the CID Director through the Death Row Unit Warden, who shall approve or disapprove the changes.
- 6. The Death Row Unit is responsible for completion of the Execution Packet, which shall include:
 - a. Execution Summary;
 - b. Religious Orientation Statement;
 - c. Copy of the Offender Travel Card;
 - d. Current Visitation List;
 - e. Execution Watch Notification;
 - f. Execution Watch Logs;
 - g. I-25 Offender's Request for Trust Fund Withdrawal;
 - h. Offender Property Documentation (PROP-05 and PROP-08); and
 - i. Other documents as necessary.
- 7. The Death Row Supervisor or the Warden's designee shall notify staff (Form 4) to begin the Execution Watch Log (Form 5).
- 8. The Execution Watch Log shall begin at 6:00 a.m. seven (7) days prior to the scheduled execution. The seven (7) day timeframe shall not include the day of the execution. The offender shall be observed, logging his activities every 30 minutes for the first six (6) days and every 15 minutes for the remaining 36 hours. The Public Information Office may request information from the Execution Watch Log on the day of execution.

- 9. The original Execution Packet and the offender's medical file shall be sent with the condemned offender in the transport vehicle to the Huntsville Unit or the Goree Unit for a female offender. The Death Row Unit Warden shall maintain a copy of the Execution Packet on the Death Row Unit.
- 10. If there are any changes necessary to the Execution Packet, staff shall notify the CID Director's Office and the Huntsville Unit Warden's Office.

B. The Day of Execution

- On the morning of the day of the execution prior to final visitation, all of the offender's personal property shall be packed and inventoried. The property officer shall complete an "Offender Property Inventory" (PROP-05) detailing each item of the offender's property. The property officer shall also complete a "Disposition of Confiscated Offender Property" (PROP-08) indicating the offender's choice of disposition of personal property.
 - a. If disposition is to be made from the Huntsville Unit a copy of the property forms should be maintained by the Death Row Unit Property Officer and the originals forwarded to the Huntsville Unit with the property.
 - b. If disposition is to be made from the Death Row Unit a copy of the property forms will be placed in the Execution Packet and the original forms maintained on the Death Row Unit through the completion of the disposition process.
 - c. The Mountain View Unit Warden shall ensure that a female offender brings personal hygiene and gender-specific items to the Huntsville Unit as appropriate.
- 2. Designated staff shall obtain the offender's current Trust Fund balance and prepare the Offender's Request for Trust Fund Withdrawal (I-25) for completion by the offender.
 - a. The following statement should be written or typed on the reverse side of the I-25, "In the event of my execution, please distribute the balance of my Inmate Trust Fund account as directed by this Request for Withdrawal." The offender's name, number, signature, thumbprint, date, and time should be below this statement. Two (2) employees' names and signatures should be below the offender's signature as witnesses that the offender authorized the form.

Execution Procedure

- b. This Request for Withdrawal form shall be delivered to the Inmate Trust Fund for processing by 10:00 a.m. CST the next business day following the execution.
- 3. A female offender may be transported to the Goree unit prior to the day of the execution. The Execution Transport Log for Female Offenders (Form 7) shall be initiated at the Mountain View Unit. The Goree Unit staff will initiate the Execution Watch Log upon arrival on the Goree Unit, permit visitation as appropriate and transport the offender to the Huntsville Unit. The Transport Log shall resume when the offender departs the Goree Unit.
- 4. The condemned offender shall be permitted visits with family and friends on the morning of the day of the scheduled execution. No media visits shall be allowed at the Goree Unit.

NOTE: Special visits (minister, relatives not on the visitation list, attorney, and other similar circumstances) shall be approved by the Death Row or Goree Unit Warden or designee. Exceptions may be made to schedule as many family members to visit prior to the offender's scheduled day of execution. These are considered to be special visits. No changes shall be made to the offender's visitation list.

- 5. The Execution Watch Log shall be discontinued when the Execution Transport Log for Male Offenders (Form 6) is initiated.
- 6. When appropriate the offender shall be escorted to 12 building at the Polunsky or the designated area at the Mountain View or Goree Unit and placed in a holding cell. The appropriate Execution Transport Log shall be initiated and the offender shall be prepared for transport to the Huntsville Unit. The offender shall be removed from the transport vehicle at the Huntsville Unit and escorted by Huntsville Unit security staff into the execution holding area.
- 7. Any transportation arrangements for the condemned offender between units shall be known only to the Wardens involved, the CID Director, as well as those persons they designate as having a need to know. No public announcement shall be made concerning the exact time, method, or route of transfer. The CID Director's Office and the Public Information Office shall be notified immediately after the offender arrives at the Huntsville Unit
- When the offender enters the execution holding area the Execution Watch Log shall immediately resume. The restraints shall be removed and the offender strip-searched.

- 9. The offender shall be fingerprinted, placed in a holding cell, and issued a clean set of TDCJ clothing.
- 10. The Warden shall be notified after the offender has been secured in the holding cell. The Warden or designee shall interview the offender and review the information in the Execution Packet.
- 11. Staff from the Public Information Office shall also visit with the offender to determine if he wishes to make a media statement and to obtain authorization, if necessary, to release the statement.
- 12. The offender may have visits with a TDCJ Chaplain(s), a Minister/Spiritual advisor who has the appropriate credentials and his attorney(s) on the day of execution at the Huntsville Unit; however, the Huntsville Unit Warden must approve all visits.
- 13. There shall be no family or media visits allowed at the Huntsville Unit.

IV. Drug Team Qualifications and Training

- A. The drug team shall have at least one medically trained individual. Each medically trained individual shall at least be certified or licensed as a certified medical assistant, phlebotomist, emergency medical technician, paramedic, or military corpsman. Each medically trained individual shall have one year of professional experience before participating as part of a drug team, shall retain current licensure, and shall fulfill continuing education requirements commensurate with licensure. Neither medically trained individuals nor any other members of the drug team shall be identified.
- B. Each new member of the drug team shall receive training before participating in an execution without direct supervision. The training shall consist of following the drug team through at least two executions, receiving step-by-step instruction from existing team members. The new team member will then participate in at least two executions under the direct supervision of existing team members. Thereafter, the new team member may participate in executions without the direct supervision of existing team members.
- C. The Huntsville Unit Warden shall review annually the training and current licensure, as appropriate, of each team member to ensure compliance with the required qualifications and training.

V. Pre-execution Procedures

- A. The Huntsville Unit Warden's Office shall serve as the communication command post and entry to this area shall be restricted.
- B. Inventory and Equipment Check
 - 1. Designated staff on the Huntsville Unit are responsible for ensuring the purchase, storage, and control of all chemicals used in lethal injection executions for the State of Texas.
 - 2. The drug team shall obtain all of the equipment and supplies necessary to perform the lethal injection from the designated storage area.
 - 3. An inventory and equipment check shall be conducted.
 - 4. Expiration dates of all applicable items are to be checked on each individual item. Outdated items shall be replaced immediately.
- C. Minister/Spiritual and attorney visits shall occur between 3:00 and 4:00 p.m. CST unless exceptional circumstances exist. Exceptions may be granted under unusual circumstances as approved by the Huntsville Unit Warden.
- D. The offender shall be served his last meal at approximately 4:00 p.m. CST.
- E. The offender shall be afforded an opportunity to shower and shall be provided with clean clothes at some time prior to 6:00 p.m. CST.
- F. The CID Director or designee, the Huntsville Unit Warden or designee and the Huntsville Unit Chaplain or a designated approved TDCJ Chaplain shall accompany the offender while in the Execution Chamber.
- VI. Set up Preparations for the Lethal Injection
 - A. One (1) syringe of normal saline shall be prepared by members of the drug team.
 - B. The lethal injection drug shall be mixed and syringes shall be prepared by members of the drug team as follows:
 - Pentobarbital 100 milliliters of solution containing 5 grams of Pentobarbital.
 - C. The drug team shall have available a back-up set of the normal saline syringe and the lethal injection drug in ease unforeseen events make their use necessary.

VII. Execution Procedures

- A. After 6:00 p.m. CST and after confirming with the Office of the Attorney General and the Governor's Office that no further stays, if any, will be imposed and that imposition of the court's order should proceed, the CID Director or designee shall give the order to escort the offender into the execution chamber.
- B. The offender shall be escorted from the holding cell into the Execution Chamber and secured to the gurney.
- C. A medically trained individual shall insert intravenous (IV) catheters into a suitable vein of the condemned person. If a suitable vein cannot be discovered in an arm, the medically trained individual shall substitute a suitable vein in another part of the body, but shall not use a "cut-down" procedure to access a suitable vein. The medically trained individual shall take as much time as is needed to properly insert the IV lines. The medically trained individual shall connect an IV administration set, and start a normal saline solution to flow at a slow rate through one of the lines. The second line is started as a precaution and is used only if a potential problem is identified with the primary line. The CID Director or designee, the Huntsville Unit Warden or designee, and the medically trained individual shall observe the IV to ensure that the rate of flow is uninterrupted.
- D. Witnesses to the execution shall be brought into the appropriate viewing area ONLY AFTER the Saline IV has been started and is running properly, as instructed by the Huntsville Unit Warden or designee.
- E. The CID Director or designee shall give the order to commence with the execution.
- F. The Huntsville Unit Warden or designee shall allow the condemned person to make a brief, last statement.
- G. The Huntsville Unit Warden or designee shall instruct the drug team to induce, by syringe, substances necessary to cause death.
- H. The flow of normal saline through the IV shall be discontinued.
- I. The lethal dose of Pentobarbital shall be commenced. When the entire contents of the syringe have been injected, the line shall be flushed with an injection of normal saline.
- J. The CID Director or designee and the Huntsville Unit Warden or designee shall observe the appearance of the condemned individual during application of the Pentobarbital. If, after a sufficient time for death to have occurred, the condemned individual exhibits visible signs of life, the CID Director or designee

- shall instruct the drug team to administer an additional 5 grams of Pentobarbital followed with a saline flush.
- K. At the completion of the process and after a sufficient time for death to have occurred, the Warden shall direct the physician to enter the Execution Chamber to examine the offender, pronounce the offender's death, and designate the official time of death.
- L. The body shall be immediately removed from the Execution Chamber and transported by a coordinating funeral home. Arrangements for the body should be concluded prior to execution.
- VIII. Employee participants in the Execution Process shall not be identified or their names released to the public. They shall receive an orientation with the Huntsville, Goree, Polunsky, or Mountain View Unit Wardens, who shall inform the employees of the TDCJ ED-06.63, "Crisis Response Intervention Support Program" (CRISP). The employees shall be encouraged to contact the Regional CRISP Team Leader following the initial participation in the execution process.

EXHIBIT B



Gregory W Gardner < ggardner@gwgardnerlaw.com>

PIA - Execution Date 2/1/18

Amy Lee <Amy.Lee@tdcj.texas.gov>

Fri, Jan 26, 2018 at 9:42 PM

To: "ggardner@gwgardnerlaw.com" <ggardner@gwgardnerlaw.com>

Cc: Erik Brown < Erik. Brown@tdcj.texas.gov>, Edward Marshall < Edward. Marshall@oag.texas.gov>, Jason Clark@tdcj.texas.gov>

Mr. Gardner,

Attached please find the information that is responsive to your open records request dated January 24, 2018.

The expiration date for the pentobarbital to be administered to your client on February 1st is: 11/09/2018.

The redactions made to the attached Storage Inventory are in accordance with Texas Government Code § 552.117(3). The remaining redactions are in accordance with Section 552.1081 and 552.136 of the Texas Government Code and Attorney General Letter Ruling OR2017-11482.

At this time the TDCJ considers your request closed.

Amy Lee

Program Specialist III

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Exhibit page 13 of 97.

From: Gregory W Gardner [mailto:ggardner@gwgardnerlaw.com]

Sent: Wednesday, January 24, 2018 1:45 PM

To: Sharon Howell <Sharon.Howell@tdcj.texas.gov>

Subject: PIA - Execution Date 2/1/18

Hello Ms. Howell,

I've attached a PIA request for my client, John D. Battaglia, who has a February 1 execution date. Thanks for your urgent attention.

- Gregory W Gardner P.O. Box 2366 Boulder, Colorado 80306 Sent via Cloze

2 attachments





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LABORATORY REPORT

Client #:

Sample: Pentobarbital 50mg/ml 2ml

Conc.: 50mg/ml

Sample ID #:

Lot#:

Date Rec'd: 12/22/2017

| Chemistry Tests: Pentobarbital Sodium | <u>Date</u> . 01/09/2018 | <i>Reported</i> 50.0 mg/mL | <u>Measured</u> 48.5 mg/mL | <u>Potency</u> 97,0 % |
|--|-----------------------------|-------------------------------|-------------------------------|--------------------------|
| Microbiology Tests: Scan RDI | <u>Date</u> 12/26/2017 | Measured | <u>Result</u> Pass | |
| Bacterial Endotoxins | 12/27/2017 | <1.00 EU/mL | Pass - | |

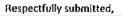
Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test

performed on each sample.

Potency: Potency is determined via USP <621> HPLC, USP<851> Spectrophotometry, and specific monograph

testing procedures.



Huntsville Unit Storage Inventory Pentobarbital 100mg/ml (5 grams)

| Date | Name of Offender | TDC# | Inventory | Amount | Amount | Inventory Total | Ref # (2) |
|----------|------------------|------------|-----------|----------------|--------|--------------------|--------------|
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Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348



EXHIBIT C

From: Amy Lee < Amy.Lee@tdcj.texas.gov > Date: January 26, 2018 at 9:44:34 PM CST

To: "ba@udashenanton.com" < ba@udashenanton.com>

Cc: Erik Brown < Erik.Brown@tdcj.texas.gov >, Edward Marshall < Edward.Marshall@oag.texas.gov >,

Jason Clark < <u>Jason.Clark@tdcj.texas.gov</u>>

Subject: RE: William Earl Rayford Execution

Mr. Anton,

Attached please find the information that is responsive to your open records request dated January 24, 2018

The expiration date for the pentobarbital to be administered to your client on January 30th is: 11/09/2018.

The redactions made to the attached Storage Inventory are in accordance with Texas Government Code § 552.117(3). The remaining redactions are in accordance with Section 552.1081 and 552.136 of the Texas Government Code.

At this time the TDCJ considers your request closed.

Amy Lee Program Specialist III

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From: Gianna Dellasera [mailto:gianna@udashenanton.com]

Sent: Wednesday, January 24, 2018 10:42 AM

To: Sharon Howell < Sharon. Howell@tdcj.texas.gov >

Cc: Bruce Anton < ba@udashenanton.com > Subject: William Earl Rayford Execution

Sharon.

Please see the attached document.

Thank you,

Gianna Della Sera Legal Assistant Udashen & Anton 2311 Cedar Springs Road Suite 250 Dallas, Texas 75201 214-468-8100 214-468-8104 (fax)

CONFIDENTIALITY NOTICE: This e-mail is sent by Udashen & Anton and may contain confidential or privileged information which is authorized to be read only by the intended recipient. Use of it by anyone other than an intended recipient is unlawful. If you have received this message in error, you are hereby notified that any use, dissemination, distribution or reproduction of this message is strictly prohibited. If you are not the intended recipient, please immediately notify me by e-mail or telephone and delete the message from your system.

Case 4:18-cv-00301 Document 2-1 Filed in TXSD on 02/01/18 Page 23 of 99

UDASHEN ANTON

BRUCE ANTON
BOARD CERTIFIED-CRIMINAL LAW AND CRIMINAL APPELLATE LAW
TEXAS BOARD OF LEGAL SPECIALIZATION

Lorie Davis Director, Correctional Institutions Division Texas Department of Criminal Justice Huntsville, Texas 77342

BA@UDASHENANTON.COM 2311 CEDAR SPRINGS RD. SUITE 250 DALLAS, TX 75201 214.468.8100 FAX 214.468.8104 WWW.UDASHENANTON,COM

Via email transmission to:

TDCJ General Counsel Sharon Howell: Sharon.Howell@tdcj.texas.gov

Re: William Earl Rayford, scheduled for execution January 30, 2018.

Dear Ms. Davis:

I represent Mr. Rayford, who is scheduled for execution on January 30, 2018. I am writing pursuant to the Texas Public Information Act, the Texas Constitution and the First, Fourth, Eighth and Fourteenth Amendments to the United States Constitution to request on Mr. Rayford's behalf the following information:

- The applicable execution protocol; [SEP]
- The specific drug or drugs, including back up, that you intend to use to carry out Mr. Rayford's scheduled execution;
- If those drugs are compounded, the date on which the compounding was performed;
- Any testing done on the drugs at any point in time, and the date and results of any such testing;
- The beyond use or expiration date of such drugs, and when and how such date(s) were established;
- The date on which the drugs were ordered, and received; and
- How the drugs have been stored since the time of compounding; [step]

I am also requesting:

- The name and quantity of all drugs in TDCJ's possession intended for

use in executions, including the date ordered and received, and whether or not the drugs are compounded;

- Any and all drug inventory logs or chain of custody documents in TDCJ's possession reflecting the purchase, possession, transfer, or disposal of lethal injection drug or drugs;
- Any testing conducted to ensure such drug or drugs potency, purity, and integrity, including the tests conducted, the date(s) of same, and the results;
- If such drug or drugs are compounded, the date they were compounded;
- If compounded, the beyond use date of each drug product / ingredient, and the documents reflecting how such date was calculated;
- How the drugs have been stored since TDCJ received them;
- Any and all documents or correspondence of any kind reflecting any effort made by TDCJ to obtain additional lethal injection drugs not currently in TDCJ's possession.

All of the requested information has been deemed public pursuant to opinions of the Open Records Division of the Office of the Attorney General.

Please provide your response, and all responsive information **ELECTRONICALLY** to my email address, <u>ba@udashenanton.com</u>.

I look forward to your timely response.

Sincerely,

Bruce Anton

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LABORATORY REPORT

Client #:

Lot#:

Sample: Pentobarbital 50mg/ml 2ml

Conc.: 50mg/ml

Sample ID #:

Date Rec'd: 12/22/2017

| Chemistry Tests: Pentobarbital Sodium | <u>Date</u> 01/09/2018 | Reported 50.0 mg/mL | <u>Measured</u> 48.5 mg/mL | <i>Potency</i> 97,0 % |
|--|---------------------------|------------------------|-------------------------------|--------------------------|
| Microbiology Tests: Scan RDI | <u>Date</u> 12/26/2017 | Measured | <u>Result</u> Pass | |
| Bacterial Endotoxins | 12/27/2017 | <1.00 EU/mL | Pass - | , 2 , |

Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test

performed on each sample.

Potency: Potency is determined via USP <621> HPLC, USP<851> Spectrophotometry, and specific monograph

testing procedures.



Huntsville Unit Storage Inventory Pentobarbital 100mg/ml (5 grams)

| Date | Name of Offender | TDC# | Inventory Total | Amount Taken | Amount Added | Inventory Total | Ref # (2) |
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Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348



EXHIBIT D

From: Amy Lee [mailto: Amy. Lee@tdcj.texas.gov]

Sent: Thursday, January 11, 2018 4:59 PM

To: Nunnally, K. Knox "Lighthorse" < KNunnally@mcguirewoods.com>

Cc: Erik Brown < Erik. Brown@tdcj.texas.gov>; Edward Marshall

<Edward.Marshall@oag.texas.gov>; Jason Clark <Jason.Clark@tdcj.texas.gov>

Subject: RE: Anthony Shore, scheduled for execution on January 18, 2018

Mr. Nunnally,

Attached please find the information that is responsive to your open records request dated January 2, 2018.

The expiration date for the pentobarbital to be administered to your client on January 18th is: 01/22/2018.

The redactions made to the attached Storage Inventory are in accordance with Texas Government Code § 552.117(3).

The Lab Report, DEA Form 222, Execution Procedure and the documents reflecting effort made by the TDCJ to ensure that the intended drugs would not cause suffering or torture were previously provided to you on 10/12/2017 pursuant to your open records request dated 10/11/17.

At this time the TDCJ considers your request closed.

Amy Lee

Program Specialist III

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From: Orand, Monica R. [mailto:MOrand@mcguirewoods.com]

Sent: Tuesday, January 02, 2018 5:02 PM

To: Sharon Howell < Sharon. Howell@tdcj.texas.gov>

Cc: Nunnally, K. Knox "Lighthorse" < KNunnally@mcguirewoods.com>; Kirk, Patti S. <pkirk@mcguirewoods.com>

Subject: Anthony Shore, scheduled for execution on January 18, 2018

Dear Ms. Howell,

Please see attached correspondence dated January 2, 2018 sent on behalf of Knox Nunnally.

Thank you,

Monica R. Orand

Practice Assistant McGuireWoods LLP JPMorgan Chase Tower 600 Travis Street Suite 7500 Houston, TX 77002-2906

T: +1 832 214 9943 F: +1 713 571 9652

morand@mcguirewoods.com VCard | www.mcguirewoods.com

This e-mail from McGuireWoods may contain confidential or privileged information. If you are not the intended recipient, please advise by return e-mail and delete immediately without reading or forwarding to others.

From: Amy Lee < Amy.Lee@tdcj.texas.gov > Date: January 12, 2018 at 6:44:54 PM CST

To: "Nunnally, K. Knox \"Lighthorse\"" < KNunnally@mcguirewoods.com >

Cc: Erik Brown < <u>Erik.Brown@tdcj.texas.gov</u>>, Jason Clark < <u>Jason.Clark@tdcj.texas.gov</u>> Subject: RE: FW: Anthony Shore, scheduled for execution on January 18, 2018

Mr. Nunnally,

The two separate storage inventory logs are different based on the size of the vials, either 100mg/ml or 50mg/ml which is listed at the top of each page of the inventory. The storage log provided to you in October listed vials that were 50mg/ml as that was intended to be used on your client at that time. The storage log that was just provided listing the 100mg/ml are the vials that are intended to be used next week. The lab and 222 provided in October pertain to both storage logs as the only difference is the size of the vials.

Amy Lee

Program Specialist III

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From: Nunnally, K. Knox "Lighthorse" [mailto:KNunnally@mcguirewoods.com]

Sent: Friday, January 12, 2018 10:05 AM To: Amy Lee < Amy.Lee@tdcj.texas.gov>

Cc: ryan.myers@bracewell.com

Subject: FW: FW: Anthony Shore, scheduled for execution on January 18, 2018

Ms. Lee:

You state that "The Lab Report, DEA Form 222, Execution Procedure and the documents reflecting effort made by the TDCJ to ensure that the intended drugs would not cause suffering or torture were previously provided to you on 10/12/2017 pursuant to your open records request dated 10/11/17."

When you responded to my October 2017 request, however, you gave me a storage inventory for 2.5 gram vials, and told me that the expiration date for those drugs was 1/22/18.

This time you gave me a storage inventory for 5 gram vials. Does this mean that the Lab Report you previously supplied (reflecting a date received of 2/6/17) and the DEA Form 222 previously supplied (reflecting drugs received on 2/2/17) apply to both the 2.5 gram and 5 gram storage inventories?

Just want to make sure there hasn't been a mix up in what you've supplied me.

Knox

K. Knox "Lighthorse" Nunnally

Senior Counsel McGuireWoods LLP JPMorgan Chase Tower 600 Travis Street Suite 7500

Houston, TX 77002-2906 T: +1 832 255 6325 M: +1 443 822 8813 F: +1 832 255 6372

knunnally@mcguirewoods.com
Bio | VCard | www.mcguirewoods.com

Huntsville Unit Storage Inventory Pentobarbital 100mg/ml (5 grams)

| Name of Offender | TDC# | Inventory | Amount | Amount | Inventory | Ref# |
|------------------|--|--|--|---|--|--|
| ——·¬ | | Total | Taken | Added | Total | (2) |
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Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348

EXHIBIT E

From: Amy Lee [mailto:Amy.Lee@tdcj.texas.gov]

Sent: Thursday, October 12, 2017 4:26 PMSent: Thursday, October 12, 2017 4:26 PM

To: Nunnally, K. Knox "Lighthorse" < KNunnally@mcguirewoods.com>

Cc: Erik Brown < Erik. Brown @tdcj.texas.gov>; Edward Marshall

<Edward.Marshall@oag.texas.gov>

Subject: RE: Anthony Shore, scheduled for execution on October 18, 2017

Mr. Nunnally,

Attached please find the information that is responsive to your request dated October 11, 2017.

The expiration date for the pentobarbital to be administered to your client on October 18th is: 01/22/2018.

The redactions made to the attached Storage Inventory are in accordance with Texas Government Code §552.117(3).

The redactions made to the attached Lab Report and DEA Form 222 are pursuant to Texas Government Codes §552.1081 and § 552.136 and the Texas Attorney General's Letter Ruling: OR2016-11482.

Also attached is the Execution Procedure and the documents reflecting effort made by the TDCJ to ensure that the intended drugs would not cause suffering or torture.

Amy Lee Legal Assistant II

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General Counsel, without the permission of the original sender. If you have received this material in error, please notify me immediately by telephone and destroy all electronic, paper, or other versions.

From: Kirk, Patti S. [mailto:pkirk@mcguirewoods.com] On Behalf Of Nunnally, K. Knox "Lighthorse"

Sent: Wednesday, October 11, 2017 9:21 AM

To: Sharon Howell <Sharon.Howell@tdcj.texas.gov>

Cc: Nunnally, K. Knox "Lighthorse" < KNunnally@mcguirewoods.com > **Subject**: Anthony Shore, scheduled for execution on October 18, 2017

Dear Ms. Howell,

Attached is correspondence to Lorie Davis from K. Knox Nunnally regarding Anthony Shore.

Please forward this to her upon receipt. This correspondence is time sensitive.

Thank you.

Patti Kirk

Practice Assistant McGuireWoods LLP JPMorgan Chase Tower 600 Travis Street Suite 7500 Houston, TX 77002-2906

T: +1 713 353 6685 F: +1 713 571 9652 pkirk@mcguirewoods.com VCard | www.mcguirewoods.com

This e-mail from McGuireWoods may contain confidential or privileged information. If you are not the intended recipient, please advise by return e-mail and delete immediately without reading or forwarding to others.

9 attachments

Huntsville Unit Storage Inventory Pentobarbital 50mg/ml (2.5 grams)

| Date | Name of Offender | TDC# | Inventory Total | Amount Taken | Amount Added | Inventory Total | Ref # |
|---------|--|---------|--------------------|-----------------|-----------------|--------------------|-------|
| 7-20-17 | Return from Supplier | , | -1 | | الو | iT | |
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Note - All offender's addresses are at 815 12th Street, Huntsville, Texas 77348



LABORATORY REPORT

Client #:

Sample: Pentobarbital Sodium

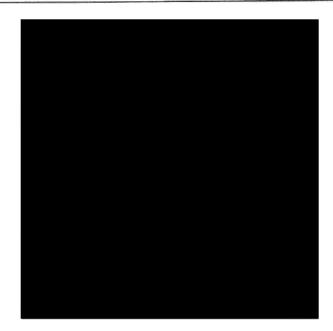
Conc.: 50 mg/ml

Lot#:

Sample ID #:

Date Rec'd: 02/08/2017

| <u>Chemistry Tests:</u> Pentobarbital Sodium | <u>Date</u> 02/10/2017 | Reported 50.0 mg/mL | <u>Measured</u> 50.5 mg/mL | Potency 101 % |
|---|---------------------------|------------------------|-------------------------------|------------------|
| Microbiology Tests: Scan RDI | <u>Date</u> 02/09/2017 | *** | | |
| Bacterial Endotoxins | 02/10/2017 | <1.00 EU/mL | Pass | |



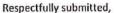
Notes:

Bacterial Endotoxins: Endotoxins are measured using USP<85> Turbidimetric procedure, with an inhibition / enhancement test

performed on each sample.

Potency: Potency is determined via USP <621> HPLC, USP<851> Spectrophotometry, and specific monograph

testing procedures.









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| 1 | 11 | IOPML | Pentobarbital | Na S | 5Pmg/ml | In: | | | | | | | | 11 | 2/2/17 |
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EXHIBIT F

James H. Ruble, PharmD, JD

August 2016

PERSONAL DATA

Birth: 6 April 1965, Coronado, California

Citizenship: United States

Family: Spouse (Ruth); three children

Address & Phone (W): University of Utah College of Pharmacy, Skaggs Pharmacy Institute,

30 South 2000 East, Room 4924, Salt Lake City, Utah, 84112

Office: (801) 581-4514

e-mail address: jim.ruble@hsc.utah.edu

EDUCATION

| <u>Degree</u> | <u>Years</u> | <u>Institution</u> |
|-------------------------------------|--------------|--------------------|
| Juris Doctor | 1999 - 2002 | University of Utah |
| Doctor of Pharmacy | 1992 - 1994 | University of Utah |
| Bachelor of Science – Pharmacy | 1989 - 1992 | University of Utah |
| Bachelor of Science – Biology | 1984 - 1989 | University of Utah |
| (Molecular & Biochemistry emphasis) | | |

LICENSURE/CERTIFICATION

| Pending | Conflict Resolution Graduate Certificate Program, University of Utah, Department of Communication (Admitted to program for 2016-2017 academic year) |
|----------------|---|
| 2014 – Present | Basic Life Support for Healthcare Providers (CPR and AED), American Heart Association |
| 2004 – Present | Registered Patent Attorney, United States Patent and Trademark Office, Reg. No. 56118 |
| 2002 - Present | Attorney, Utah State Bar, Member No. 09426 |
| 1994 – 1996 | Registered Pharmacist – Pennsylvania Board of Pharmacy License No. RP041317R (expired 9/30/1996) |
| 1992 – Present | Registered Pharmacist – Utah Division of Occupational and Professional Licensing, License No. 153627-1701 (expires 9/30/2017) |
| 1986 – 1988 | Certified Pulmonary Function Technician (CPFT), National Board for Respiratory Care |
| 1985 – 1997 | Advanced Cardiovascular Life Support (ACLS), American Heart Association |
| 1985 – 1997 | Basic Life Support (BLS). American Heart Association |

EMPLOYMENT / PROFESSIONAL EXPERIENCE

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2013 - Present Associate Professor (Clinical), Department of Pharmacotherapy, College of Pharmacy, Skaggs Pharmacy Institute, University of Utah, Salt Lake City, Utah
 2010 - Present Adjunct Assistant Professor, Department of Pharmaceutics and Pharmaceutical Chemistry, College of Pharmacy, Skaggs Pharmacy Institute, University of Utah, Salt Lake City, Utah
 2010 - 2013 Assistant Professor (Clinical), Department of Pharmacotherapy, College of Pharmacy, Skaggs Pharmacy Institute, University of Utah, Salt Lake City, Utah
 2006 - 2011 Visiting Faculty, Roseman University of Health Sciences, South Jordan, Utah
 1995 - 2009 Clinical Assistant Professor, Department of Pharmacotherapy, College of Pharmacy, Skaggs Pharmacy Institute, University of Utah, Salt Lake City,

Utah Non-academia Positions – Health Care

2016 – Present Ombudsman, University of Utah Health Sciences, Office of the Associate Vice President for Faculty and Academic Affairs, School of Medicine, Salt Lake City, Utah 2009 - 2016Clinical Pharmacist, Department of Pharmacy Services, University of Utah Health Care, Salt Lake City, Utah Manager, Infusion Pharmacy, Department of Pharmacy Services, University 2007 - 2009of Utah Health Care, Salt Lake City, Utah Sterile Compounding/IV Admix Clinical Pharmacist, Department of 2004 - 2007Pharmacy Services, University of Utah Health Care, Salt Lake City, Utah 2000 - 2001Staff Pharmacist, Target Stores Pharmacy, Centerville, Utah 1996 - 1999Clinical Pharmacist in Ambulatory Neurology and Neurosurgery, Department of Pharmacy Services, University of Utah Health Care, Salt Lake City, Utah Clinical Pharmacist in Drug Information, Department of Pharmacy Services, 1995 - 1996University of Utah Health Care, Salt Lake City, Utah 1994 - 1995Pediatric Pharmacy Team Coordinator, Pharmacy Department, Geisinger Medical Center, Janet Weis Children's Hospital, Danville, Pennsylvania Staff Pharmacist, Pharmacy Department, Primary Children's Medical Center, 1992 - 1994Salt Lake City, Utah Pharmacist Intern, Pharmacy Department, Primary Children's Medical 1989 - 1992Center, Salt Lake City, Utah Clinical Technologist, Sleep Disorders Center, University of Utah Health 1988 - 1990Care, Salt Lake City, Utah 1985 - 1988Pulmonary Function Technician, Pulmonary Laboratory, University of Utah Health Care, Salt Lake City, Utah

1985 – 1985 Anesthesiology Technician, Anesthesiology Workroom, University of Utah Health Care, Salt Lake City, Utah

Non-academia Positions - Law and Consulting

| 2013 – Present | Founder and Member, Salus Consulting, LLC, Bountiful, Utah |
|----------------|--|
| 2004 – 2006 | Principal Attorney, Wasatch Intellectual Property Services, LLC, North Salt Lake, Utah |
| 2002 - 2005 | Associate Attorney, Pate Pierce & Baird, PC, Salt Lake City, Utah |
| 2001 - 2001 | Law Clerk, Jones Waldo Holbrook & McDonough, PC, Salt Lake City, Utah |
| 2000 - 2000 | Independent Consultant, Christensen & Jensen, PC, Salt Lake City, Utah |

HONORS, RECOGNITIONS & AWARDS

- 2016 P3 Class Teacher of the Year, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 2015 Leadership in Ethics Education Award, Daniels Fund/David Eccles School of Business, University of Utah, Salt Lake City, Utah
- 2015 Outstanding Professor Award, Hinckley Institute, University of Utah, Salt Lake City, Utah
- 2014 Distinguished Teaching Award & Teacher of the Year, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 2014 P4 and P2 Class Teacher of the Year, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 2011 Distinguished Teaching Award & Teacher of the Year, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 2011 P2 Teacher of the Year, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 2005 Partners-in-Caring Award, University of Utah Health Care, Salt Lake City, Utah
- 1995 Employee Recognition Award for Outstanding Service, Geisinger Medical Center, Danville, Pennsylvania
- 1993 Ewart Swinyard Scholarship, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 1992 Facts and Comparisons Award for Excellence in Clinical Communications, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 1992 McNeil Pharmaceuticals Award for Outstanding Achievement in Pharmacy Administration, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 1991 Allen and Hanburys Scholarship, College of Pharmacy, University of Utah, Salt Lake City, Utah
- 1991 Faculty Scholarship, College of Pharmacy, University of Utah, Salt Lake City, Utah

RESEARCH AND SCHOLARLY WORK

Grants

2016 - Present Treatment patterns, patient outcomes, and healthcare charges in hemophilia

at Hemophilia Treatment Centers in the Intermountain West. Principal Investigator: David Stenehjem, PharmD, BCOP

Biogen/IDEC

Direct Costs: \$462,500 Total Costs: \$613,738

Role: Co-Investigator (%, TBD)

2012 – 2014 Evaluation, Research, Survey and Recommendations: Physician Dispensing

Exemption from Pharmacy Licensure. Requirement RFP Solicitation No.

MP12023, State of Utah

Principal Investigator: Mark Munger, PharmD Direct Costs: \$67,000 Total Costs: \$67,000

Role: Co-Investigator (40%)

2011 – 2013 Promoting the Pharmacy Profession as a Career Pathway for Female Students

and Students from Ethnically Diverse Backgrounds Principal Investigator: James H. Ruble, PharmD, JD

Direct Costs: \$3,500 Total Costs: \$3,500 Educational Resources Development Council

Role: Principal Investigator (100%)

2012 – 2012 Evaluation of buffer solutions and impact of gas sterilization processes

Principal Investigator: Mark Munger, PharmD Direct Costs: \$15,000 Total Costs: \$15,000

BARD Access Systems, Inc. Role: <u>Co-Investigator (50%)</u>

1998 – 1998 Comprehensive evaluation of psychometric assessment tools in Alzheimer's

disease

Principal Investigator: Gary Oderda, PharmD, MPH

Direct Costs: \$10,000 Total Costs: \$10,000

Novartis Pharmaceuticals Corporation

Role: Co-Investigator (50%)

PUBLICATIONS

Peer-Reviewed Journal Articles

- 13. **Ruble JH.** Evaluation of US Federal Legislation for Opioid Abuse: 1973-2016. *J Pain Palliat Care Pharmacother*. 2016 [accepted for publication]
- 12. Feehan M, Durante R, **Ruble JH**, Munger MA. Qualitative Interviews about Pharmacist Prescribing in the Community Setting. *Am J Health-Syst Pharm*. 2016 [accepted for publication]
- 11. **Ruble JH.** Tools for "decloaking" the elephant in the room: Conflict-of-interest, Shared Decision-Making and Patient-Centered Care [Commentary]. *J Pain Palliat Care Pharmacother*. 2015 Jun;29(2):173-7. doi: 10.3109/15360288.2015.1037519.

- 10. **Ruble JH.** The "death" of lethal injection as we know it? An opportunity to reflect on the role of chemical execution in the US criminal justice system [Commentary]. *J Pain Palliat Care Pharmacother*. 2014 Sep;28(3):276-81. doi: 10.3109/15360288.2014.941133. Epub 2014 Aug 14.
- 9. Munger MA, **Ruble JH**, Nelson SD, Ranker L, Petty RC, Silverstein, S, et al. National Evaluation of Prescriber Drug Dispensing. *Pharmacotherapy*. 2014 Oct;34(10):1012-21. doi: 10.1002/phar.1461. Epub 2014 Jul 23.
- 8. **Ruble JH.** Prescriber-Pharmacist Collaboration: Re-engineering the Partnership to Optimize Pain Patient Care [Commentary]. *J Pain Palliat Care Pharmacother*. 2013 Dec;27(4):365-6. doi: 10.3109/15360288.2013.849322. Epub 2013 Oct 21.
- 7. **Ruble JH.** Distribution of Controlled Substances in the US Supply Chain: Where does the Compass Point? [Commentary]. *J Pain Palliat Care Pharmacother*. 2012 Sep;26(3):251-3. doi: 10.3109/15360288.2012.703983.
- 6. Shrewsbury R, Augustine S, Birnie C, Nagel K, Ray D, **Ruble J,** Scolaro K, Athay Adams J. AACP Report: Assessment and Recommendations of Compounding Education in AACP Member Institutions. *Am J Pharm Educ.* 2012 Sep 10;76(7):S9. doi: 10.5688/ajpe767S9.
- 5. **Ruble JH**. Off-label Prescribing of Medications for Pain: Maintaining Optimal Care at an Intersection of Law, Public Policy and Ethics. *J Pain Palliat Care Pharmacother*. 2012;26:146-52.
- 4. **Ruble JH**. Baxter v. Montana, Libertarianism, and End-of-Life: The Ripe Time for a Paradigm Shift. *J Pain Palliat Care Pharmacother*. 2010 Sep;24(3):263-70. doi: 10.3109/15360288.2010.502214.
- 3. **Ruble J**, Matsuo F. Antiepileptic-induced cutaneous drug reactions: Incidence, mechanisms, and management. *CNS Drugs*. 1999;12(3): 215-36.
- 2. **Ruble J**, Muncey LA. Beta-adrenergic agonists in the treatment of asthma. *J Pharm Care Pain Symptom Control*. 1997;5(4): 49-56.
- 1. Goeser S, **Ruble J**. Melatonin: Historical and clinical perspectives. *J Pharm Care Pain Symptom Control*. 1997;5(1):37-49.

Posters, Abstracts, and Reports

- 6. Bowman N, **Ruble J**, Crouch BI. Homemade Play-Dough: Money Saving and Potentially Life-Threatening? North American Congress of Clinical Toxicology. Clin Toxicol 2016 [accepted for publication].
- 5. Skrabal MZ, Downs GE, Carter RA, Eagerton DH, Franson KL, Hritcko PM, Jungnickel PW, Kissack JC, **Ruble J**, Torrado C. (2016). *Marijuana Use Task Force (MUTF): Considerations for Schools Regarding Marijuana Use by Students, Faculty, and Preceptors*. Poster session presented at American Association of Colleges of Pharmacy Annual Meeting, Anaheim, California

- 4. Blumenthal D, Stephens S, Nyman H, Jennings B, **Ruble J**, et al. (2013). *Rapid development and longitudinal incorporation of interprofessional education simulations into the pharmacy curriculum*. Poster session presented at American Association of Colleges of Pharmacy Annual Meeting, Chicago, Illinois
- 3. **Ruble J**, Edwards D, Schmidt J, et al. (2003). *Medication Use Review: Infliximab use in the ambulatory clinic infusion center at University Health Care*. Report presented to Pharmacy Administration, University of Utah Health Care, Salt Lake City, Utah
- 2. **Ruble J**, Constantino T, Godsey C, et al. (1998). *Topiramate (TPM) use in refractory epilepsy patients ineligible for surgical treatment [Abstract #100231]*. Poster session presented at American Epilepsy Society 52nd Annual Meeting, Sheraton Convention Center, San Diego, California
- 1. Forshew DA, **Ruble J**, Bromberg MB. (1998). A survey of ALS/MND specialists for medication preferences for relief of symptoms associated with ALS/MND. Platform Presentation. Poster session presented at The 9th International Symposium on ALS/MND, Park Hilton, Munich, Germany

Book Chapters

1. **Ruble JH**. Compounded medications in pain management: customized rational polypharmacy. In: Aronoff GM, editor. Medication management of chronic pain: what you need to know. Publication pending, Trafford Publishing. 2016.

Letters

- 2. **Ruble JH**, Brixner DA. Comment & Response: Outpatient Pharmacy Expenditures for Children with Serious Chronic Illness in California, 2010-2012. *JAMA*. 2016;315(7):706. doi:10.1001/jama.2015.16978.
- 1. Subach RA, **Ruble J**. Misprint of dosage interval for liposomal doxorubicin hydrochloride [Letter]. *Am J Health Syst Pharm*. 1996;53(14):1727.

Other Publications

- 5. **Ruble JH.** Pharmacoeconomics an evolving tool in health technology assessment. Division of Medical Ethics and Humanities Newsletter, School of Medicine, University of Utah. June 2016. Available at: http://medicine.utah.edu/internalmedicine/medicalethics/newsletters/index.php
- 4. **Ruble J**. Impact safety, efficiency, and the bottom line with premixed IV products. *Pharmacy Purchasing & Products*. 2008;5(2):34,36,38.
- 3. **Ruble J**. USP Chapter <797> Compliance: Important legal issues. *Pharmacy Purchasing & Products*. 2008;5(6):16,18,20.
- 2. **Ruble J**, Hill GK. Inadvertent Public Disclosure and Possible Loss of Intellectual Property Rights. *Nutraceutical Business & Technology* 2005;1(5):34-40.
- 1. **Ruble J**, Koberstein W, ed. Special Report: The Secure IPO Launch Plan A Virtual Roundtable. *BioExecutive International* 2005;1(4):58-67.

Ruble, Page 6

EDITORIAL EXPERIENCE

Editorial Board Member

Journal of Pain & Palliative Care Pharmacotherapy

Reviewer Experience

Reviewer for Journal of Managed Care Pharmacy, Alexandria, Virginia, USA

Reviewer for *Journal of Pain & Palliative Care Pharmacotherapy*, Informa Healthcare USA

Reviewer for *Hospital Pharmacy Journal*, ThomasLand Publishers, St. Louis, Missouri, USA

Reviewer for *Pharmacist's Letter*, Therapeutic Research Center, Stockton, California, USA Reviewer for *BMC Research Notes*, BioMed Central, London, UK

PRESENTATIONS

Meeting Presentations

Local/Regional/National

- 04/2017 Reducing Risk and Maintaining Empathy: Professional Practice Tips for Risk Management & Strengthening Relationships. Anticoagulation Forum Boot Camp. Los Angeles, California
- 11/2016 Educator's Session Formative and Summative Assessment in Pharmacy Law Education. American Society for Pharmacy Law Fall Seminar. Austin, Texas
- 05/2016 Moral Distress and Moral Fatigue in Health Care Professionals. Project ECHO Burn and Soft Tissue Injury. University of Utah Burn Center. Salt Lake City, Utah
- 01/2016 Reducing Risk and Maintaining Empathy: Professional Practice Tips for Risk Avoidance, Risk Mitigation & Strengthening Relationships. Anticoagulation Forum Boot Camp. Salt Lake City, Utah
- 11/2014 Pharmacy and the Continuum of Lethal Injection. American Society for Pharmacy Law Fall Seminar. Indian Wells, California
- 11/2014 Educator's Session Teaching Federal Pharmacy Law. American Society for Pharmacy Law Fall Seminar. Indian Wells, California
- 10/2014 Prescription Drugs and Poisonings: Exploring the Landscape Legal Perspective. Utah Poison Control Center 60th Anniversary Symposium. Salt Lake City, Utah
- 11/2013 Compounding Paradigm Shift: a new regulatory landscape. American Society for Pharmacy Law Fall Seminar. Jacksonville, Florida
- 11/2012 Pharmacy Compounding and Meningitis Tragedy Update: What lessons can we learn? Utah Board of Pharmacy, Salt Lake City, Utah
- 09/2010 Criminal Liability for Compounding Errors: A discussion of recent cases. Utah Society of Health System Pharmacists, Annual Meeting, Salt Lake City, Utah
- 07/2009 Is Compounding illegal or unethical? A discussion of law and ethics in pharmaceutical compounding. University of Utah College of Pharmacy Pharmacotherapy Department Seminar

- 04/2009 Equipoise and Clinical Research in an Academic Medicine Environment. University of Utah Health Care, Ethics Committee, Educational Presentation, Salt Lake City, Utah
- 08/2007 Investigational New Drug Applications: Information for Principal Investigators and IRB Panel Members. Institutional Review Board Annual Retreat, University of Utah, Salt Lake City, Utah
- 08/2006 INDA's Investigational New Drug Applications: An introduction in 10 questions. Institutional Review Board Annual Retreat, University of Utah, Salt Lake City, Utah
- 11/1998 Ten questions (and answers) about your medications for Parkinson's Disease. St. George/Southern Utah Parkinson's Disease Association, Senior Center, St. George, Utah
- 05/1998 Know Your Medications: Ten questions (and answers) about your medications for Parkinson's Disease. Annual Meeting, Utah Chapter, American Parkinson's Disease Association. Moran Eye Center Auditorium, University of Utah, Salt Lake City, Utah
- 09/1997 Drug therapies for neurologic disorders. 2nd Annual Salt Lake Veterans Affairs Hospital Gerontological Nursing Conference. Wyndham Hotel Convention Center, Salt Lake City, Utah
- 11/1995 Temporal Variation in Pharmacotherapy and the Drug Regulatory Process.

 Department of Pharmacy Practice, College of Pharmacy, University of Utah, Salt Lake City, Utah

Grand Rounds Presentations and Invited Presentations

- 10/2016 Assisted Suicide: Implications for Families and Society. Fall Symposium. J. Reuben Clark Law School, Brigham Young University, Provo, Utah
- 09/2016 Keynote Speech: Time and Opportunity. White Coat Ceremony. College of Pharmacy, University of Utah, Salt Lake City, Utah
- 02/2015 Lethal injection in the United States criminal justice system: A modern Kairos? Hinckley Institute at The University of Utah, Salt Lake City, Utah
- 08/2014 Art Imitating Life Reflecting on the fictional world of *Harry Potter* and realities in pharmacy and pharmaceutical sciences. Eccles Health Sciences Library, University of Utah, Salt Lake City, Utah
- 01/2011 Pharmacist Liability: A case study. Grand Rounds, Department of Pharmacy Services, University of Utah Health Care, Salt Lake City, Utah
- O5/2006 Applied Bioethics and Withdrawal of Life-Support in Dying Patients. Grand Rounds, Department of Pharmacy Services, University Health Care, University of Utah, Salt Lake City, Utah
- 11/2003 Fundamentals of Intellectual Property for the Neurologist and Neuroscientist.
 Grand Rounds, Department of Neurology, University of Utah School of Medicine,
 Salt Lake City, Utah

Continuing Education Presentations

- 09/2016 Death With Dignity. Continuing Legal Education Webinar Program, American Bar Association, Health Care Law Section
- 06/2016 Hemophilia Managed Care Review Board Health Economics and Pharmacoeconomics Assessment Analyzing Available Data to Assess the Value of Treatment Options and Collaborative Care Management. Web-based Continuing Education Program. Philadelphia, Pennsylvania
- 09/2015 Death With Dignity, Pharmacy and HB 391. Utah Society of Health-System Pharmacists, McKay-Dee Hospital, Ogden, Utah
- 02/2014 Pharmacist Providers: Professional evolution or passing fancy? Utah Therapeutics and Pharmacy Law Continuing Education Program. Roseman University of Health Sciences. Salt Lake City and Logan, Utah
- 09/2013 Compounding Paradigm Shift: Public Policies and Changes in Regulatory Landscape. Utah Society of Health-System Pharmacists, Salt Lake City, Utah
- 08/2013 Hot Potato: A Chronicle of Non-Sterile Compounding. Utah Pharmacists Association, Layton, Utah
- 11/2012 Conflict, Compassion and Communication: Ethical Reasoning in Drug Shortages and Resource Allocation. Greater New York Hospital Association, Metropolitan New York
- O5/2012 Pharmacy Law Review and Refresher Course. University of Utah College of Pharmacy Continuing Pharmacy Education Program, Health Sciences Education Building, University of Utah, Salt Lake City, Utah. (Full-day CPE program in Pharmacy Law and Ethics)
- O5/2011 Pharmacy Law Review and Refresher Course. University of Utah College of Pharmacy Continuing Pharmacy Education Program, Health Sciences Education Building, University of Utah, Salt Lake City, Utah. (Full-day CPE program in Pharmacy Law and Ethics)
- O3/2011 Ethics Panel Discussion: A continuum of pharmacy issues at end-of-life. Panel participant and moderator. Mid-winter meeting: Utah Society of Health-System Pharmacists and University of Utah College of Pharmacy. Health Sciences Education Building, University of Utah, Salt Lake City, Utah
- 11/2010 Pharmacist Liability: A case study. Department of Pharmacy Services, Intermountain Medical Center. Murray, Utah
- 03/2010 USP <797> -- Planning, implementation and enforcement: successes and struggles. Southern Nevada Society of Health-System Pharmacists, Mid-year Meeting. Henderson, Nevada
- 02/2010 Pharmacist Liability: A case study. Utah Society of Health-System Pharmacists Annual Meeting. Davis Convention Center, Layton, Utah
- 01/2010 Brands, Generics, and Pay-for-Delay: Implications in Patient Care. University of Southern Nevada, Winter CPE Meeting. South Jordan, Utah, and Logan, Utah
- 11/2009 Disclosing a Dispensing Error: Ethical Reasoning. Utah Pharmacists Association, Fall Meeting. Wyndam Hotel and Convention Center, Salt Lake City, Utah

| 05/2009 | Complying with Controlled Substances Laws While Maintaining Compassion for Patients. Continuing Education Program, University of Southern Nevada, South Jordan, Utah |
|---------|--|
| 10/2008 | Conflict-of-Interest. Fall Continuing Education Program, University of Utah College of Pharmacy, Salt Lake City, Utah |
| 12/2007 | Applied Bioethics and Withdrawal of Life-support in Dying Patients. 14th Annual Winter CE Program, University of Arizona College of Pharmacy, Park City, Utah |
| 12/2006 | Review of Medicare/Medicaid Fraud and Abuse. 13th Annual Winter CE Program, University of Arizona College of Pharmacy, Park City, Utah |
| 12/2006 | Dealing with Conflict of Interest Ethical Issues. 13th Annual Winter CE Program, University of Arizona College of Pharmacy, Park City, Utah |
| 04/2006 | Pharmacist Refusal to Dispense: An overview of legal and ethical issues. Utah Pharmacists Association Annual Meeting, Dixie Center, Saint George, Utah |
| 12/2005 | Pharmacist Refusal to Dispense: An overview of legal and ethical issues. Annual Winter CE Program, University of Arizona College of Pharmacy, Park City, Utah |
| 12/2004 | Negligence Update: Pharmacists Duty to Warn. 11th Annual Winter CE Program, University of Arizona College of Pharmacy, Park City, Utah |
| 12/2004 | Business Law Primer for Pharmacists. 11th Annual Winter CE Program, University of Arizona College of Pharmacy, Park City, Utah |
| 12/2003 | Federal and State Administrative Law: FDA, FTC, DEA and State Boards. 10th Annual Winter CE Program, University of Arizona College of Pharmacy, Park City Utah |
| 12/2003 | Federal Legislation and Pharmacy Practice Update. 10th Annual Winter CE Program, University of Arizona College of Pharmacy, Park City, Utah |
| 10/2003 | Navigating Federal Drug Law: 1987-2003: Significant Legislation, Rx-to-OTC switch, Drug Importation. Annual Meeting, Utah Society of Health-System Pharmacists, University of Utah College of Pharmacy, Salt Lake City, Utah |
| 04/1999 | Medical Assistant In-service Lecture Series: Medication injections and commonly used oral medications in the ambulatory clinic. Medical Assistants, University of Utah Hospitals & Clinics, Salt Lake City, Utah |
| 10/1998 | Treatment of Parkinson's Disease: New tricks and old treats. Continuing Education |

Industrial Presentations

O5/1998 Parkinson's disease, Multiple sclerosis, and Amyotrophic Lateral Sclerosis, Partnership For Care Program, Athena Home Pharmacy Division, Athena Neurosciences, Embassy Suites, South San Francisco, California

Program, College of Pharmacy, University of Utah, Salt Lake City, Utah

- 03/1997 Idiopathic Parkinson's Disease. SmithKline Beecham Pharmaceuticals, Intermountain Sales Team, Chart House Restaurant, Salt Lake City, Utah
- 12/1997 Presenter, Pfizer Inc., Cerebyx: A new advance in seizure control. Paracelsus Family Practice Department, Salt Lake City, Utah

Media Appearances

8/2015 "Printing Pills" *Science Friday with Ira Flatow*. National Public Radio. (aired 8/7/2015) http://www.sciencefriday.com/segments/venomous-frogs-a-polar-bear-world-record-and-printing-pills/

PROFESSIONAL ORGANIZATIONS & SERVICE

| 2015 – Present | Member, American Society of Health-System Pharmacists (ASHP) |
|----------------|---|
| 2015 – Present | Member, American Pharmacists Association (APhA) |
| 2014 – Present | Member, Rho Chi Society – Pharmacy Honor Society |
| 2013 – Present | Member, American Society for Pharmacy Law (ASPL) |
| 2013 – Present | Faculty Advisor, National Community Pharmacists Association Chapter |
| 2012 – Present | Member, American Association of Colleges of Pharmacy (AACP) |
| 2002-Present | Member, Utah State Bar Association |
| 1996 – Present | Member, Utah Society of Health-System Pharmacists |
| 1994 – Present | Member, Phi Lambda Sigma Pharmacy Leadership Society |
| 1990 – 1992 | Member, American Pharmacists Association – Academy of Student Pharmacists |

Professional Service

| 2015 – Present | Chair, Pharmacy Law Educator's Sub-Committee, American Society for Pharmacy Law (ASPL) |
|----------------|---|
| 2015 – Present | Task Force Member, American Association of Colleges of Pharmacy, AACP Task Force on Marijuana Use by Students, Faculty and Preceptors |
| 2010 – 2012 | Task Force Member, American Association of Colleges of Pharmacy, AACP Task Force to Evaluate Compounding Instruction in US Pharmaceutical Education |
| 2009 - 2011 | Board Member-at-Large, Utah Society of Health-System Pharmacists |
| 2002 –2004 | Co-Chair, Utah Society of Health-System Pharmacists, Newsletter Committee |

Public Service

| 2013 – Present | Pharmacy Compounding Task Force. Utah Board of Pharmacy, Division of Occupational & Professional Licensing, Department of Commerce, State of Utah |
|----------------|---|
| 2013 – 2014 | Health Information Workgroup: State of Utah Health Innovation Model Grant. State of Utah Department of Health. Center for Health and Informatics. CFDA 93.624 |

2010 – Present Presenter, Area Health Education Centers, Presented information on

pharmacy careers and interactive pharmacy compounding demonstration for

Health Careers Summer Camp for Rural Health Scholars Program at

Southern Utah University

UNIVERSITY COMMITTEE ACTIVITIES

University Level – University of Utah

2006 – 2009 Member, Institutional Review Board

University of Utah Health Care System

2007 – Present Hospital Ethics Committee

Chair, 2015 – Present Co-Chair, 2013 – 2015

Clinical Ethics Consultation Team, 2007 – present

2009 – 2010 USP <797> Sterile Compounding Task Force, Department of Pharmacy

Services

College Level – University of Utah College of Pharmacy

| 2015 - Present | Member, College of Pharmacy Scholastic Standards Committee |
|----------------|---|
| 2013 – Present | Member, College of Pharmacy Inter-Professional Education (IPE) Committee |
| 2012 – 2016 | Member and P1 Steward, College of Pharmacy Curriculum Development Committee |
| 2011 - 2014 | Member, College of Pharmacy Admissions Committee |
| 2011 - Present | Member, College of Pharmacy Student Mentoring Committee |
| 2009 - 2011 | Member, College of Pharmacy Diversity Advisory Committee |

CURRENT & PAST AREAS OF TEACHING RESPONSIBILITY

Courses Directed

| 2015 – Present | PCTH 7314: Community Practice (OTC & Self-Care) , Pharmacotherapy Department, College of Pharmacy, University of Utah |
|----------------|---|
| 2010 – Present | PCTH 5226: Pharmaceutical Compounding and Drug Delivery Systems , Pharmacotherapy Department, College of Pharmacy, University of Utah |
| 2009 – Present | PCTH 7313/PHARM 7142: Pharmacy Law, Ethics, and Risk . Pharmacotherapy Department, College of Pharmacy, University of Utah |
| 2008 – Present | PCTH 7436: Ethical Dilemmas in Pharmacotherapy and Pharmaceutical Sciences . Pharmacotherapy Department, College of Pharmacy, University of Utah |

| 2011 – Present | Co-instructor, PHCEU 7975: Journal Club -PhD, Pharmaceutics and Pharmaceutical Chemistry Department, College of Pharmacy, University of Utah |
|----------------|---|
| 2010 – Present | Co-Instructor, PHARM 5113: Basics in Pharmaceutical Sciences , College of Pharmacy, University of Utah |
| 2009 – Present | Co-Instructor, PHCEU 5125: Dosage/Drug Delivery , Pharmaceutics and Pharmaceutical Chemistry Department, College of Pharmacy, University of Utah |
| 2008 – 2010 | Primary Instructor, PCTH 7603: Home Health Clerkship , Pharmacotherapy Department, College of Pharmacy, University of Utah |
| 2004 – Present | Co-Instructor, PCTH 5112: Profession of Pharmacy , Pharmacotherapy Department, College of Pharmacy, University of Utah |
| 2009 – 2012 | Contributor, PCTH 7321: Intro to Clerkships , Pharmacotherapy Department, College of Pharmacy, University of Utah |
| 2011 – Present | Contributor, PCTH 6500: Research Ethics , Pharmacotherapy Department, College of Pharmacy, University of Utah |
| 2012 – Present | Contributor, PCTH 6890: Research Seminar I , Pharmacotherapy Department, College of Pharmacy, University of Utah |
| 2012 – Present | Contributor, PCTH 7100: Clinical Seminar I , Pharmacotherapy Department, College of Pharmacy, University of Utah |

Other Didactic Lectures

| 2016 | Basal Ganglia – Clinical Pharmacology, Medical Students, University of Utah School of Medicine, Salt Lake City, Utah |
|-------------|--|
| 1998 | Pharmacotherapy of Neurological Disorders. Physical Therapy Students. College of Health, University of Utah, Salt Lake City, Utah |
| 1998 – 1999 | Medical Assistant In-service Lecture Series: Medication injections and commonly used oral medications in the ambulatory clinic. Medical Assistants, University of Utah Health Care, Salt Lake City, Utah |

Department/Division Conferences

| 11/2011 | Communication of Risk in Pharmacotherapy: More than just a four-letter word. Department of Pharmacotherapy, College of Pharmacy, University of Utah, Salt Lake City, Utah |
|---------|---|
| 05/2011 | Ethics of High Cost Oncology Drugs: Identifying Victims, Villains, and Values. Department of Pharmacy Services, University of Utah Health Care, Salt Lake City, Utah |
| 09/2010 | Risk Management and the Lexicon of Pharmacy Practice. Task Force on Future Curricular Revision, College of Pharmacy, University of Utah, Salt Lake City, Utah |

| 08/1999 | New Antiepileptic Drugs: Advantages and Disadvantages. Clinical Sciences Conference, Department of Neurology, University of Utah, Salt Lake City, Utah |
|---------|---|
| 08/1998 | Pharmacological Treatment of Parkinson's Disease: Current issues and future directions. Clinical Sciences Conference, Department of Neurology, University of Utah, Salt Lake City, Utah |
| 05/1997 | Antidepressant selection in patients with neurologic disorders. Clinical Sciences Conference, Department of Neurology, University of Utah. Salt Lake City, Utah |
| 06/1997 | Botulinum toxin in neurologic, ophthalmologic, and laryngeal disorders. Pharmacy Department, University Hospital, Salt Lake City, Utah |

James H. Ruble, R.Ph., Pharm.D., J.D. SALUS CONSULTING, L.L.C. 3362 South 400 East Bountiful, Utah 84010

August 12, 2016

Michael J. Biles King & Spalding LLP 401 Congress Avenue, Ste. 3200 Austin, Texas 78701

Re: Case No. _____; Wood, et al. v. Collier, et al., In the United States
District Court for the Southern District of Texas, Houston

Dear Mr. Biles:

My name is James H. Ruble. On behalf of Plaintiffs Jeffrey Wood, Rolando Ruiz, Robert Jennings, Terry Edwards and Ramiro Gonzales in the above-referenced case, you have asked me to provide a precise scientific description of the process of compounding pentobarbital in suport of Plaintiffs' Motion for Preliminary Injunction. The opinions I express in this report are made to a reasonable degree of scientific certainty.

I reside in Bountiful, Utah, located in the metropolitan area of Salt Lake City. I have been a registered pharmacist in the State of Utah since 1992. I earned a Doctor of Pharmacy, a Juris Doctor, a Bachelor of Science in Pharmacy, and a Bachelor of Science in Biology from the University of Utah, in Salt Lake City. I am a pharmacist at the University of Utah Health Care System, and I am an associate professor (clinical) in the Department of Pharmacotherapy and an adjunct assistant professor in the Department of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah College of Pharmacy. I teach pharmacy law, health care ethics, and pharmaceutical compounding to professional pharmacy students and graduate students. My curriculum vitae, detailing prior positions, Honors, Research and Scholarly Work, Publications, and Presentations, is attached as Exhibit A.

In preparation of this report, I reviewed the U.S. Food and Drug Administration ("FDA") Guidance on Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"), FDA Guidance on Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal FDCA, and the guidelines provided in:

1. United States Pharmacopeia ("USP") General Chapter <797> Pharmaceutical

¹ Available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052

² Available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377051

- Compounding -Sterile Preparations ("USP <797>");
- 2. USP General Chapter <795> Pharmaceutical Compounding Nonsterile Preparations ("USP <795>");
- 3. USP General Chapter <85> Bacterial Endotoxins Test ("USP <85>");
- 4. USP General Chapter <71> Sterility Tests ("USP <71>"); and
- 5. USP Monograph for Pentobarbital Sodium Injection.

These USP sections are from version USP 37/NF 32 and are designated as "official" through 30 April 2015.

A. PHARMACEUTICAL COMPOUNDING

The 2013 Drug Quality and Security Act (Public Law 113-54-Nov. 27, 2013)³ established two types of pharmaceutical compounding: traditional and non-traditional. These two activities are frequently referred to as "503 A" compounding and "503 B" compounding, respectively. Traditional (503 A) compounding does not involve the creation of drugs from scratch. Rather, it uses active and inactive ingredients to meet the individual needs of a specific, identifiable patient that for medical reasons cannot be met with an FDA-approved product, according to a legal prescription for an individual patient.

Non-Traditional (503 B) compounding also involves the use of active and inactive pharmaceutical ingredients to compound pharmaceutical preparations. However, the final preparation is not intended for a specific, identifiable patient; thus is not "patient specific" but is intended for general sales and distribution. Non-traditional compounding is commonly referred to as "outsourced" compounding and resembles drug manufacturing more than it does the professional practice of pharmacy. Unlike manufacturers, compounding pharmacies are generally not subject to the drug approval process and the rigorous checks and regulatory procedures required under current Good Manufacturing Practice For Finished Pharmaceuticals ("cGMPs").⁴ Non-traditional compounders must nonetheless register with the FDA and acknowledge the jurisdiction and authority of the FDA to inspect their facilities. Whether a drug is compounded by a Traditional or Non-traditional compounder, the FDA does not verify the safety or effectiveness of these drug preparations or the quality of their manufacture. These compounded products thus remain outside the FDA regulatory framework that otherwise ensures these qualities in manufactured pharmaceutical drugs.

The intended use of a compounded drug customarily dictates the formula to be used, compounding method(s), appropriate storage conditions, and calculation of an appropriate "beyond use date" ("BUD"). The intended uses of drugs are frequently supported by one or more published descriptions in a life science, clinical science, or pharmaceutical science database. This publication process is fundamental to the concept of "evidence based medicine" ("EBM")⁵ and

Exhibit page 55 of 97.

³ Available at http://www.gpo.gov/fdsys/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

⁴ 21 CFR Part 211. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.crm?CFRPart=211

⁵ See e.g., Evidence-Based Medicine Working Group. Evidence-based medicine. A new approach to teaching the practice of medicine. JAMA. 1992;268(17):2402-2425.

Good Clinical Practice⁶ philosophies. For purposes of the writing of this report, I conducted searches in the National Library of Medicine (PubMED) database and the International Pharmaceutical Abstracts ("IPA") database, using the terms "pentobarbital" and "execution." According to these databases, there is no published scientific description of, or formula for, the process of compounding pentobarbital for use in executions. As such, it is highly probable there is no scientific, evidence-based formula existing in the public domain for this use.

There are, however, USP guidelines that govern the methods by which compounding pharmacies should prepare pharmaceutical preparations for medicinal use via intravenous ("IV") route of administration. I describe below these general guidelines and how they might be used to guide a pharmacy in compounding pentobarbital sodium injection.

B. THE PROCESS FOR COMPOUNDING PENTOBARBITAL FOR MEDICINAL USE VIA INTRAVENOUS INJECTIONS

Pentobarbital is a short-acting barbiturate licensed by the FDA for human use as a sedative, hypnotic, pre-anesthetic, and anticonvulsant, in the emergency control of certain acute convulsive episodes.⁷ In most of the clinical indications of pentobarbital sodium injection, it is administered either as an Intramuscular ("IM") injection into a large muscle or as a direct injection into an IV catheter.

In circumstances in which commercial pentobarbital sodium injection is unavailable for use, either due to shortage or other supply chain disruption, some pharmacies may have the equipment and expertise to prepare a compounded "copy" of the commercial product. This would entail use of the bulk active pharmaceutical ingredient ("API") and inactive ingredient s. An API is any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation. Pentobarbital sodium salt is the bulk powder form needed to make finished compounded preparations of pentobarbital. Without pentobarbital sodium salt API, it is not possible to compound pentobarbital sodium injection. Quality API is pivotal to a quality final product.⁸

The compounding of pentobarbital for IV administration must be conducted as "sterile" compounding because the preparation is administered directly into the systemic circulation of the body and bypasses mechanisms which protect humans from microbial infection and other potentially harmful toxins including, but not limited to, endotoxins and pyrogens. USP <797> (attached to this Report as Exhibit B), established in 2004, provides professional standards and

⁶ Good Clinical Practice ("GCP") is developed by the International Conference on Harmonization ("ICH") of Technologies. The FDA has guidance about use of GCP in U.S. Health Care, available at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

⁷ Pentobarbital sodium injection, product labeling. Available at http://dailymed.nlm.hih.gov/dailymed/drugInfo.cfm?setid=5c380ab0-4386-48b6-80ab-ca594b23bc74

⁸ I recently reviewed the current availability of pentobarbital sodium salt API in the United States by consulting primary commercial sources upon which U.S. compounding pharmacies rely for purchase of bulk chemical APIs. From my review, I concluded that pentobarbital API in bulk powder form is not currently available for sale for purchase by compounding pharmacies in the U.S. for use in compounded pentobarbital preparations.

guidance in pharmaceutical compounding of sterile preparations. Preparations compounded in conformance with USP <797> are referred to as "compounded sterile products" ("CSP"s). USP <797> establishes three levels of sterile compounding, based on risk of contamination, to wit: low- risk; medium-risk; and high-risk CSPs. Pentobarbital sodium injection compounding would be designated as a high-risk CSP because a non-sterile bulk powder API is incorporated into a finished, compounded preparation. It is then subjected to a terminal sterilization process, which is required under USP <797> for high risk compounded sterile products. This may be accomplished by any number of physical, chemical, or mechanical methods. In many compounding pharmacies, the preferred method of terminal sterilization is through use of membrane filtration.

In accordance with USP standards and definitions, a solution intended for parenteral administration is titled an "injection." A compounded pentobarbital sodium injection must contain the pentobarbital sodium API and one or more inactive ingredients to form the solution. One of these inactive ingredients must be a liquid vehicle to serve as a diluent to dissolve the solid powder API form. Water is the primary diluent used to prepare the commercial (manufactured) form of pentobarbital sodium injection, and it is highly probable that compounding pharmacies are using water in their pentobarbital sodium injection CSPs. In addition, compounding pharmacies may be including other inactive ingredients, e.g., propylene glycol, alcohol, hydrochloric acid, sodium hydroxide. Small amounts of these ingredients may be added, for example, to adjust pH, tonicity, and solubility of the finished preparation.

The manual combination or mixing of these ingredients, that is, the "compounding" process, must be carried out under specific environmental conditions, using equipment that is properly calibrated and maintained, and performed by personnel that are highly trained and whose competency and aseptic technique is verified at regular• intervals. Sterile compounding of pentobarbital sodium injection must be done in a Direct Compounding Area that has ISO 5 quality airflow within a primary engineering control (e.g., a HEAP-filtered, horizontal laminar airflow workbench) that is located within a clean room that has ISO 7 quality airflow, as well as numerous additional design features. The airflow in the clean room and in the primary engineering controls must be certified at regular intervals by certified HVAC engineers. In addition, USP <797> has robust expectations for cleaning and maintenance of the clean room and compounding equipment, as well as quality assurance processes and quality control testing of the equipment for microbial and other non-viable particulate contaminants. Compliance with these USP <797> requirements is mandatory.

As can be inferred from the previous paragraph, pharmaceutical compounding of sterile products is a highly technical process that requires precision and has a very narrow tolerance for error. Pharmacies that choose to provide compounded sterile products must make substantial commitments for facilities, equipment, skilled personnel, training, quality programs (i.e., quality assurance, quality control, quality improvement), standard operating practices, and record retention practices. Moreover, compounded sterile products such as pentobarbital sodium injection have additional risks in view of the utilization of nonsterile bulk API in the compounding process. While I do not have access to the exact process used by the compounding pharmacy in this case, my compounding knowledge and experience suggests the following steps, not necessarily in this order, nor limited to only these steps:

- Obtain pre-work materials, inventory and controlled substance record documentation, labeling, review master compounding and batch form records
- Collect container of bulk API (i.e., pentobarbital sodium powder) and other pharmaceutical ingredients to be used in compounding the preparation, as well as the accessories used to compound (e.g., syringes, needles, containers, disinfecting chemicals, etc.)
- Conduct hand hygiene and proper donning of sterile compounding garb (e.g., gloves, hair cover, mask, shoe covers, gown)
- Enter compounding clean room, preparing laminar airflow workbench, arrange materials in organized fashion
- Conduct compounding activities, weighing proper amount of bulk API, measuring proper volume of diluent and other inactive ingredients
- Using aseptic technique, add API and inactive ingredients into a container and observe powder to completely dissolve into solution
- Upon dissolution, use membrane filtration to terminally sterilize the finished preparation
- Check the integrity of the membrane filter to ensure it has remained intact
- If required, obtain samples for additional quality testing (e.g., sterility testing, bacterial endotoxin testing, potency testing, purity testing, pH testing, etc.

As previously stated, this is a general description of the process, and there could be several other steps depending on the operations of the pharmacy facility and number of preparations being compounded.

C. BEYOND-USE DATING AND PRODUCT LIFE CYCLE

Traditional and Non-Traditional compounding pharmacies do not have access to the sophisticated equipment (e.g., spectroscopes, chromatographs, calorimeters, etc.) for qualitative and quantitative analysis that are typically found in pharmaceutical manufacturer establishments. This sophisticated equipment is important for measuring chemical, physical, and biological parameters to extend shelf-life of CSPs. Accordingly, Traditional and Non-Traditional compounders must limit their batch "production" sizes and settle for relatively short "beyond use dates" and thus limited commercial opportunities.

A "beyond use date" ("BUD") is defined in USP <797> as "the date or time after which a CSP shall not be stored or transported. The BUD is determined from the date and time the preparation is compounded." BUDs are typically assigned on the basis of professional experience and judgment and rarely based on batch-specific chemical analysis. Thus, a BUD is an empiric determination. Although BUD is sometimes used interchangeably with "expiration date," these terms have different meaning. Expiration dates are assigned to manufactured products based on rigorous analytical and performance testing. The "expiration" date of FDA regulated pharmaceuticals is a qualified assurance that they retain their integrity over specified periods of time. This assurance is more difficult to do with compounded drugs. In the traditional compounding setting, it is also often unnecessary, as a particular drug is mixed pursuant to a licensed prescriber's order for an individual patient for immediate use.

Longer BUDs ("extended BUDs") can be established for CSPs using empirical data based on extended stability and sterility testing. This testing is conducted by a laboratory or, in the absence of such data, can be calculated according to the recommended ranges established under USP < 797>. The calculation of an extended BUD is dependent on numerous variables, including, pivotally, the stability and sterility of the subject compounded drug:

Pharmaceutical stability depends on the purity and concentration of specific ingredients, packaging and environmental exposure and storage . . . Small changes in any of those variables can cause rapid loss of drug strength or much shorter than expected shelf-life. . . . even the most expert and caring pharmacist's visual, olfactory or other professional judgment, in the absence of scientific testing results about sterility and stability of compounded pharmaceuticals can be dangerously wrong.

Newton, David and Dunn, Bernard, A Primer on USP Chapter <797> "Pharmaceutical Compounding-Sterile Preparations," and USP Process for Drug and Practice Standards, p. 11.9

Even after it is assigned to a CSP, a BUD can be affected dramatically by subsequent storage conditions. CSPs (such as pentobarbital sodium injection) need to be kept in very particular conditions, relating to the stability and properties of the medicines in question. If not stored properly, CSPs can be damaged and rendered unusable. The multiplicity of variables underscores the impossibility of reliable date certain BUDs and the importance of subsequent testing - and stability and sterility testing in particular -multiple times over a drug's shelf life, not just shortly after it is compounded. *Id.; see also* USP Chapter <795> "Stability Criteria and Beyond-Use Dating."

As set forward in USP <797>, these are the empiric BUDs for CSPs:

| Risk Level | Room Temp | Refrig | Freeze |
|-----------------|-----------|---------|---------|
| Low | 48 hr | 14 days | 45 days |
| Low (12 hr BUD) | 12 hr | 12 hr | n/a |
| Medium | 30 hr | 9 days | 45 days |
| High | 24 hr | 3 days | 45 days |

Thus, the maximum BUD (timed from the day and hour of preparation) that can be assigned to these products is:

- 24 hours, if CSPs are stored at controlled room temperature
- 3 days, if CSPs are stored at a cold temperature (i.e., refrigerated)

⁹ Available here: www.nhia.org/members/documents/usp 797 primer.pdf

¹⁰ See id. at 40.

• 45 days, if CSPs are stored in a solid, frozen temperature.

While it is impossible to assess the accuracy of a BUD without knowing detailed information about the compound, the raw ingredients, the compounders, and the testers, it is possible to review the relevant science and codes to recognize the unreliability of a stated "expiration date" beyond an intended immediate use of the compounded drug.

I hope you find this information helpful. If I can provide further clarification or explanation, please let me know. As you are aware, I was not asked to apply these standards or practices to the State of Texas's use of compounded pentobarbital for purposes of execution by lethal injection. As always, the application of scientific protocols to a specific set of facts or circumstances could affect my views and opinions because the protocols and/or tests that must be taken into account could compel a different discussion. Please let me know if I can be of further assistance as your litigation proceeds.

Date: August 12, 2016

Sincerely,

James H. Ruble

Am 10 Pan

EXHIBIT G

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

| JEFFERY WOOD, ROLANDO | § | |
|-------------------------------------|-------------|-------------------------------|
| RUIZ, ROBERT JENNINGS, | § | |
| TERRY EDWARDS, AND | § | |
| RAMIRO GONZALES | § | |
| Plaintiffs, | | CIVIL ACTION NO. 4:16-cv-2497 |
| | § § | |
| $\mathbf{vs.}$ | § | |
| | § | |
| BRYAN COLLIER, | § | DEATH PENALTY CASE |
| Executive Director, | § | |
| Texas Department of Criminal | § § § | |
| Justice, | § | PLAINTIFF JEFFERY WOOD IS |
| | § | SCHEDULED FOR EXECUTION |
| LORIE DAVIS, | § | ON AUGUST 24, 2016 |
| Director, Correctional | § § | |
| Institutions Division, | § | PLAINTIFF ROLANDO RUIZ IS |
| Texas Department of Criminal | § | SCHEDULED FOR EXECUTION |
| Justice, | § § § | ON AUGUST 31, 2016 |
| | § | |
| JAMES JONES, | § | REMAINING PLAINTIFFS ARE |
| Senior Warden, Huntsville Unit | § | SCHEDULED FOR EXECUTION |
| Huntsville, Texas, | § | IN SEPTEMBER, OCTOBER, |
| | § | AND NOVEMBER, 2016 |
| and | § | |
| | § | |
| UNKNOWN EXECUTIONERS; | § § | |
| Defendants. | § | |

DECLARATION OF DAVID B. WAISEL, MD IN SUPPORT OF PLAINTIFFS' TEMPORARY RESTRAINING ORDER

Pursuant to 28 U.S.C. § 1746, I hereby declare as follows:

- 1. My name is David B. Waisel. I am over the age of eighteen and competent to testify to the truth of the matters contained herein.
- 2. I am a practicing anesthesiologist at Boston Children's Hospital and an Associate Professor of Anaesthesia, Harvard Medical School. I have been

practicing clinical anesthesiology, primarily pediatric anesthesiology, for approximately 23 years.

- 3. I have been asked by the attorneys who represent Plaintiffs to provide an expert medical and scientific opinion about whether there is a substantial risk that the State's use of expired or contaminated pentobarbital will cause Plaintiffs severe pain during their executions.
- 4. It is my understanding that the State of Texas intends to execute Plaintiffs by a single injection of compounded pentobarbital. It also is my understanding that although the State tests its supply of compounded pentobarbital for potency, sterility, and the presence of contaminates when it receives the drug from its supplier, it does not re-test the drug shortly before it is used for lethal injection.
- 5. For example, I understand that on or about April 7, 2016, an unknown laboratory tested the compounded pentobarbital that it intends to use for Mr. Wood's execution for potency (93.8%). There is no way to know whether the drug is still of adequate potency more than four (4) months later because a single test at a single point in time does not tell us anything about the long term stability of the drug particularly where, as here, the drug is intended for use far beyond the USP recommended beyond use date. Moreover, a compounded drug that has only been tested once, four months before its intended use, could have become degraded or contaminated particularly if the storage conditions are sub-optimal.
- 6. Compounded drugs have a high risk of improper potency, composition, contaminants, impurities, and degradation that could cause pain

upon administration. In my opinion, the State's failure to re-test the compounded drug shortly before it is used for lethal injection leads to a substantial risk that the inmate will suffer pain during the execution.

- 7. In preparing this declaration, I reviewed the June 2012 Execution Protocol of the Texas Department of Criminal Justice ("TDCJ").
- 8. Given the well-known problems associated with compounding pharmacies, I only use compounded drugs when there is absolutely no alternative.
- 9. While sub-par anesthetics or incompetent administration can cause a variety of serious problems, I focus here only upon problems that could cause serious or severe pain upon or immediately after intravenous injection. These potential problems with using drugs fall into two basic categories: improper potency and unintended additives. Each category has a number of subcategories.
- 10. Potency is the amount of drug required to produce a specific effect. If a solution is assumed to have 10 mg/cc of a drug, but only has 5 mg/cc of a drug, the amount of the drug given which is based on the assumed concentration of 10 mg/cc will not provide the intended effect. If the pentobarbital is not in the assumed concentration, the inmate will receive less than the protocol requires. This smaller dose creates a substantial risk of a prolonged death, including periods of difficulty breathing, which would feel like suffocating to death.
- 11. Anesthetic solutions, such as compounded pentobarbital, which have expired or gone beyond their "shelf life," lose potency. If an expired drug is used, although the concentration may be correct (in that there is 10 mg/cc), the effect of the concentration of the expired drug will be less than the effect of the same

concentration for a non-expired drug. This would lead to the same effect upon injection as use of a sub-potent drug: prolonged death with periods of what feels like suffocation.

- 12. Administration of a sub-potent first dose (through either an incorrect concentration or a sub-potent drug) could lead to a need for a second dose. Because the Director does not have clear instructions about when to administer the second dose (particularly with regard to timing), a delayed second dose could lead to a longer period of difficulty breathing, leading to substantial pain and suffering.
 - 13. Unintended additives can occur in a variety of forms and ways.
- 14. Because of inadequate laboratory procedures, the drug may be contaminated by another drug that itself may cause severe pain. For example, it may be mixed with the antibiotic penicillin, present in many pharmaceutical labs. The penicillin family is one of the most prescribed antibiotics; 10% of people report an allergy to penicillin. Allergic individuals who take penicillin may have an anaphylactic reaction, including angioedema, which causes swelling around the face, particularly of the mouth and tongue, and great difficulty breathing. Patients report that a severe anaphylactic reaction is like suffocating to death.
- 15. Pain on injection also may arise from the chemical composition of a solution, resulting in a direct or indirect irritant effect. Direct pain occurs immediately. Indirect pain occurs 10 20 seconds after injection, due to a local chemical reaction. Factors that affect pain on injection from chemical and composition errors include osmolality and acid-base status. Improper

compounding, contaminants, and poor quality ingredients can result in incorrect osmolality or acid-base status.

- 16. Osmolality is the concentration of the solutes (such as sodium and chloride) in the blood. Normal human osmolality is approximately 290 milliosmoles/liter. Injected drugs that have a non-physiologic osmolality (that is, an osmolality different than normal human blood) cause significant venous irritation.
- 17. Acid-base status is assessed by pH. Normal human blood pH is about 7.4. Acid solutions with a pH of less than 4 or alkaline solutions with a pH more than 11 cause extreme pain when injected into veins.
- 18. Impurities in the lethal injection solution also can be extremely problematic. Improper compounding and testing procedures may leave fine particles undetectable by the naked eye in the solution, or larger particles that would not be detected by an untrained eye. These particles can cause great irritation to the vein, resulting in extraordinary pain.
- 19. The fact that Texas has conducted executions using pentobarbital of inmates (approximately 30 have occurred thus far, to my knowledge) have not generated reports of problems is not dispositive of the safety, efficacy, or reliability of compounded pentobarbital as used to induce anesthetic coma in human beings. Only when a drug has been tested systematically on thousands of subjects, with their consent, can one begin to reliably assess how an untested use of a drug will affect human subjects. We do not have relevant data in similar populations for pentobarbital. Because we do not have sufficient data, there is no way to know, in

any given case, how an overdose of pentobarbital will affect basically healthy inmates.

I declare under penalty of perjury that the foregoing is true and accurate. Executed this $16^{\rm th}$ day of August 2016.

ABLLL

David B. Waisel, MD

Date Prepared: July 1, 2016

Name: David B. Waisel, M.D.

Office Address: Boston Children's Hospital

Department of Anesthesiology, Perioperative and Pain Medicine

300 Longwood Avenue, Bader 3

Boston, MA 02115

Home Address: 15 Beechwood Road

Wellesley MA 02482

Work Phone: 617-355-6457

Work Email: David.Waisel@childrens.harvard.edu

Work FAX: 617-730-9237

Place of Birth: Harrisburg, Pennsylvania

Education

| 1987 | B.A. | Pre-Medicine | Lehigh University |
|------|----------------|--------------|--------------------|
| 1989 | M.D. | Medicine | Medical College of |
| | Humanities Sch | nolar | Pennsylvania |

Postdoctoral Training

| 7/1989- | Intern | Internal Medicine | Wilford Hall Medical |
|---------|-----------------|--------------------------|------------------------|
| 6/1990 | | | Center |
| 7/1990- | Resident | Anesthesiology | Wilford Hall Medical |
| 6/1992 | | | Center |
| 7/1992- | Senior Resident | Pediatric Anesthesiology | Children's Hospital |
| 6/1993 | | | Boston/Harvard Medical |
| | | | School |
| 9/1993- | Fellow | Medical Ethics | Harvard Medical School |
| 5/1994 | | | |

Faculty Academic Appointments

| 7/1992- | Clinical Fellow | Anaesthesia | Harvard Medical School |
|---------|---------------------|-------------|-------------------------|
| 6/1993 | | | |
| 7/1993- | Research Fellow | Anaesthesia | Harvard Medical School |
| 6/1994 | | | |
| 7/1997- | Clinical Assistant | Anesthesia | F. Edward Hebert School |
| 6/1999 | Professor | | of Medicine, Uniformed |
| | | | Services University of |
| | | | Health Sciences |
| 8/1999- | Assistant Professor | Anaesthesia | Harvard Medical School |
| 6/2006 | | | |
| 7/2006- | Associate Professor | Anaesthesia | Harvard Medical School |

Appointments at Hospitals/Affiliated Institutions

| 7/1993- | Assistant in Anesthesia | Department of Anesthesiology, | Children's Hospital Boston |
|---------|-----------------------------|---------------------------------|----------------------------|
| 6/1994 | | Perioperative and Pain Medicine | |
| 7/1994- | Attending | Department of Anesthesia | Wilford Hall Medical |
| 6/1999 | | | Center |
| 1/1995- | Bioethics Consultant | Office of Medical Ethics | Wilford Hall Medical |
| 6/1999 | | | Center |
| 1/1998- | Director | Office of Medical Ethics | Wilford Hall Medical |
| 6/1999 | | | Center |
| 9/1999- | Associate Clinical | Office of Ethics | Children's Hospital Boston |
| 1/2012 | Ethicist | | |
| 8/1999- | Assistant in Anesthesia | Department of Anesthesiology, | Children's Hospital Boston |
| 6/2000 | | Perioperative and Pain Medicine | - |
| 7/2000- | Associate in Anesthesia | Department of Anesthesiology, | Children's Hospital Boston |
| 6/2003 | | Perioperative and Pain Medicine | |
| 7/2003- | Senior Associate in | Department of Anesthesiology, | Children's Hospital Boston |
| | Anesthesia | Perioperative and Pain Medicine | |
| 9/2006- | Co-Chair, Education | Program for Patient Safety and | Children's Hospital Boston |
| 1/2012 | Committee | Ouality | - |

Other Professional Positions

Major Administrative Leadership Positions

| Local | | | |
|----------------|--|---------|-----------------------------|
| 1995-1998 | Chief, Pediatric Anesthesiology | | Wilford Hall Medical Center |
| 1995-1996 | Assistant Chair for Resident Education | n, | Wilford Hall Medical Center |
| | Department of Anesthesiology | | |
| 1997-1998 | Assistant Chair for Research, Departm | nent of | Wilford Hall Medical Center |
| | Anesthesiology | | |
| 2000-2011 | Chair, Fellow Selection Committee | | Children's Hospital Boston |
| Exhibit page 6 | 9 of 97. | 2 | |

| 2003-2013 | Program Director, Pediatric Anesthesiology | Children's Hospital Boston |
|-----------|--|----------------------------|
| | Fellowship | |
| 2006-2012 | Chair, Education Committee, Program for | Children's Hospital Boston |
| | Patient Safety and Quality | |
| 2014- | Program Director, Pediatric Regional | Boston Children's Hospital |
| | Anesthesiology Fellowship | |

National and International

| 2002-204 | Councilor | Anesthesia History Association |
|-----------|--------------------------|---------------------------------------|
| 2004-2008 | Treasurer | Anesthesia History Association |
| 2008-2010 | Vice President | Anesthesia History Association |
| 2007-2009 | President | Pediatric Anesthesiology Program |
| | | Director's Organization |
| 2009-2011 | Immediate Past President | Pediatric Anesthesiology Program |
| | | Director's Organization |
| 2009- | Board of Trustees | Wood Library-Museum of Anesthesiology |
| 2012-2014 | Treasurer | Wood Library-Museum of Anesthesiology |

Committee Service

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| Locai | | |
|-----------|--------------------------------------|---|
| 1994-1999 | Bioethics Committee | Wilford Hall Medical Center |
| | 1994-1997 | Chair |
| 1994-1998 | Education Committee | Department of Anesthesiology, |
| | | Wilford Hall Medical Center |
| | 1995-1996 | Chair |
| 1994-1998 | Clinical Competence Committee | Department of Anesthesiology, |
| | • | Wilford Hall Medical Center |
| | | Member |
| 1994-1998 | Quality Improvement Committee | Department of Anesthesiology, |
| | | Wilford Hall Medical Center |
| | | Member |
| 1997-1999 | Institutional Review Board | Wilford Hall Medical Center |
| | | Member |
| 1998-1999 | Patient Care Council | Wilford Hall Medical Center |
| | | Member |
| 1998-1999 | Credentials Committee | Wilford Hall Medical Center |
| | | Member |
| 1999 | Awards Committee | Society of Air Force Clinical Surgeons 46 th |
| | | Annual Meeting |
| 1999-2012 | Ethics Advisory Committee | Children's Hospital Boston |
| | | Member |
| 2001-2012 | Graduate Medical Education Committee | Children's Hospital Boston |
| | | Member |
| 2001-2013 | Education Committee | Department of Anesthesiology, |
| | | |

| | | Perioperative and Pain Medicine, Children's Hospital Boston Member |
|-----------|--|---|
| 2002-2003 | Leadership Committee for ACGME Competencies | Children's Hospital Boston Member |
| 2003 | Organizational Ethics Consultation: Hospital Policy for Caring for Jehovah's Witnesses | Children's Hospital Boston Member |
| 2003-2013 | Clinical Competency Committee | Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston Member |
| 2004-2010 | Ethics Leadership Group | Harvard Medical School Member |
| 2005-2013 | Executive Committee | Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston Member |
| 2006-2012 | Senior Clinical Leadership Quality Council | Children's Hospital Boston Member |
| 2007-2013 | Information Services Steering Committee | Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital Boston Member |
| 2007 | Henry K. Beecher Prize in Medical Ethics 2007 | Harvard Medical School Award Committee Member |
| 2008 | Henry K. Beecher Prize in Medical Ethics 2008 | Harvard Medical School Award Committee Member |
| 2009 | Henry K. Beecher Prize in Medical Ethics 2009 | Harvard Medical School Award Committee Member |

Regional

National and International

| 1995-2010 | Committee on Ethics | American Society of Anesthesiologists |
|-----------|--|---------------------------------------|
| 2000-2002 | Task Force on Ethics | Council of Medical |
| | | Specialties Society, Representing the |
| | | American Society of Anesthesiologists |
| 2000-2002 | Working Group on Education about Gifts | American Medical Association, |
| | to Physicians | Representing the American Society of |
| | | Anesthesiologists |
| 2004-2012 | Education Committee | Society of Pediatric Anesthesia |
| 2007- | Oral Board Examiner | American Board of Anesthesiology |

Professional Societies

| 1989- | American Society of Anesthesiologists | Member |
|-------|---------------------------------------|----------------------------|
| 1992- | Society for Pediatric Anesthesia | |
| | 2004-2012 | Education Committee |
| 1995- | Anesthesia History Association | |
| | 2002-2004 | Councilor |
| | 2004-2008 | Treasurer |
| | 2008 | Vice President |

Grant Review Activities

Editorial Activities

- Editor, Bulletin of Anesthesia History (2012-2014)
- Editor-in-Chief, Journal of Anesthesia History (2015-)
- Editor, Section on Humanities in Medicine, Journal of Clinical Anesthesia (2016-)
- Guest Editor. Unfamiliar Ethical Issues. Int Anes Clin 2015;53(3)
- Ad hoc Reviewer
 - o Anesthesiology
 - o Journal of Clinical Anesthesia
 - o Journal of Clinical Ethics
 - o Bulletin of Anesthesia History
 - o Annals of Internal Medicine
 - o Anesthesia and Analgesia
 - o Mayo Clinic Proceedings
 - o British Medical Journal Quality and Safety

Honors and Prizes

| 1994 | Wood Library-Museum of Anesthesiology Fellowship | Wood Library-Museum of Anesthesiology | Fellowship to provide support to study history at the Wood Library-Museum of Anesthesiology |
|----------------|--|--|--|
| 1994-1995 | Golden Apple Award | Department of Anesthesiology, Wilford Hall Medical Center | For outstanding teacher of the year |
| 1996-1997 | Golden Apple Award | Department of Anesthesiology, Wilford Hall Medical Center | For outstanding teacher of the year |
| 2002 | David M. Little Prize | Anesthesia History Association | For the best work of anesthesia history published in the previous year in English |
| 2004 | Honorable Mention for David M. Little Prize | Anesthesia History Association | For the best work of anesthesia history published in the previous year in English |
| 2007 | Excellence in Tutoring | Harvard Medical School | For excellence in tutoring |
| Exhibit page 7 | 72 of 97. | 5 | |

Award 2009 Anesth

Anesthesiology

Anesthesiology

for Patient - Doctor III

Selected by

Trainees Face Ethical,

Practical and

Relational Challenges in Obtaining Informed

Consent.

Anesthesiology as one of twelve 2009 highlighted article that exemplifies the mission of Anesthesiology

Selected by

Anesthesiology as one of twelve 2009 highlighted article that exemplifies the mission of Anesthesiology

Report of Local Teaching and Training

Teaching of Students in Courses

| 2001-2007 | Hospital Skills Day for rising third year | 2.5 hours contact time per day for 2 days |
|-----------|---|--|
| | medical students. | per year, 2 hours prep time per year |
| | Instructor/Harvard Medical School | |
| 2003-2007 | IN750M.J Patient – Doctor III | 2.5 hours contact time per week for 24 |
| | Tutor/Harvard Medical School | weeks per year, 2 hours per week prep time |

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)

2006-2012 PERCS-Anesthesia 9-15 hours contact per year, 8 hours prep time per year

Clinical Supervisory and Training Responsibilities

1997-1999 Surgical and Pediatric ICU Ethics Teaching 8 hours contact time per month, 2 hours preparation time per month

Laboratory and Other Research Supervisory and Training Responsibilities

Formally Supervised Trainees

| 1996-1998 | Affleck PJ, Waisel DB, Cusick JM, Van Decar T. Recall of risks following labor epidural |
|-----------|---|
| | analgesia. J Clin Anesth 1998;10:111-4. |
| 1996-1998 | Scheu KL, Waisel DB. Regional anesthesia equipment checkout recommendations: A case |
| | report and discussion. J Clin Anesth 1998;10:502-5. |
| 2003-2004 | Elder J, Waisel DB. Case report of the one-armed anesthesiology resident. J Clin Anesth |

6

Exhibit page 73 of 97.

2004;16:445-8.

Formal Teaching of Peers (e.g., CME and other continuing education courses)

| 1995-1999 | ACLS & PALS | 4 hours contact time per course, 4-6 courses per year |
|-----------|---|--|
| | ACLS & PALS | Boston, MA |
| 1997 | APLS | Lecture, 2 hours contact time |
| | APLS | Boston, MA |
| 1998 | Anesthesia issues for the pediatrician: pain management, conscious sedation, preoperative evaluation, Pediatrics for the Practitioner 35 th Annual Teaching Conference, Texa | Lecture, 4 hours contact time |
| 2005-2009 | Ethics in health care theories and cases. Harvard Bioethics Course | 1 hour contact time per group, 3 groups/year |

| Local Invite | d Presentations |
|---------------------|---|
| 1994 | The history and future of informed consent. |
| | Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital |
| | Boston |
| 1998 | The physician in pre-World War II German. Healer and harbinger of death: Implications |
| | for medical ethics today. |
| | Maimonides Society of San Antonio |
| 1998 | Obligations to the professional community. |
| | Frontiers in Pediatrics, The San Antonio Military Pediatric Center |
| 1998 | Ethical issues in organ donation. |
| | Texas Organ Sharing Alliance |
| 1999 | Ethical issues related to anesthetic practice. |
| | San Antonio Society of Anesthesiologists |
| 1999 | Physician aid-in-dying. |
| | San Antonio Society of Psychiatry |
| 1999 | Ethics in battlefield medicine. |
| | Wilford Hall Medical Center |
| 2000 | Stratifying informed consent. |
| | Department of Anesthesia, New England Medical Center |
| 2001 | Perioperative management of Jehovah's Witnesses. |
| | Harvard Consortium on Ethics, Harvard Medical School |
| 2001, 2003 | Conference on informed consent in pediatric patients. |
| | Department of Medicine, Children's Hospital Boston |
| 2002 | Ethical issues related to caring for patients with mental retardation. |
| | Ethics Forum. Massachusetts General Hospital, Boston. |
| 2002 | Distribution of scarce resources. |
| | Harvard Consortium on Ethics, Harvard Medical School |
| 2002 | Social capital in the operating room. |
| | Department of Anesthesiology, Perioperative and Pain Medicine, Children's Hospital |
| | Boston |
| 2003 | Difficulties during anesthesia residency. |
| 1. 11. 14 | 74 . 007 |

| | Department of Anesthesia, Boston Medical Center |
|------|---|
| 2004 | "Being a good citizen in medicine." |
| | Department of Medicine, Children's Hospital Boston |
| 2004 | Pediatric perioperative DNR orders. |
| | Department of Neurosurgery, Children's Hospital Boston |
| 2005 | "Being a good citizen in medicine." |
| | Department of Medicine, Children's Hospital Boston |
| 2005 | Social capital in the operating room. |
| | Department of Urology, Children's Hospital Boston |
| 2005 | Being a jerk affects patient care and efficiency: social capital in the operating room. |
| | Department of Anesthesia and Critical Care, Beth Israel Deaconess Medical Center |
| 2006 | Physician participation in capital punishment. |
| | Department of Urology, Children's Hospital Boston |
| 2006 | Physician participation in capital punishment. |
| | Department of Surgery, Children's Hospital Boston |
| 2007 | Ethics jeopardy. |
| | Department of Urology, Children's Hospital Boston |
| 2011 | Hearts and minds. |
| | Keynote Address, Children's Hospital Boston Academy Retreat |
| 2015 | Graduation Speech, University of Connecticut Anesthesiology Residency Program |
| 2016 | Clinical Ethics |
| | Featured speaker, Journal Club, Department of Ophthalmology, Boston Children's Hospital |
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Report of Regional, National and International Invited Teaching and Presentations

Invited Presentations and Courses

| Regional | |
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| 2002 | Informed refusal. |
| 2004 | Perioperative DNR orders. |
| | Harvard Medical School Anesthesia Review |
| 2006 | Ethical Aspects of refusing transfusion therapy in minors. |
| | Practical Aspects of Pediatric Anesthesia |
| 2010 | The development of anesthesiology during World War II. |
| | Ellison Pierce Symposium |
| 2010 | Invited speaker. Grand Round: PERCS. Anesthesia, Critical Care and Pain Medicine, Beth Israel Dead |
| 2013 | Invited Grand Rounds speaker. Social Capital. Boston Medical Center Anesthesia/Surgery Joint Grand anesthesiology) |

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| 1995 | The role of the anesthesiologist in physician-assisted death. |
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| | American Society of Anesthesiologists Annual Meeting |
| 1996 | Should the HIV-infected anesthesiologist tell his or her patient? |
| | American Society of Anesthesiologists Annual Meeting |
| 1996 - 1999 | "Don't tell my mom!" Abortion and the minor, confidentiality and production pressure. |
| | American Society of Anesthesiologists Annual Meeting |

| 1997 | Do business ethics count in anesthesiology? Workshop on Practical Bioethics for the |
|------|--|
| | Anesthesiologist. |
| | American Society of Anesthesiologists |
| 1997 | Can ethics be taught? |
| 100= | American Society of Anesthesiologists Annual Meeting |
| 1997 | A model curriculum for teaching bioethics. |
| 1007 | American Society of Anesthesiologists Annual Meeting |
| 1997 | Ethical issues in the operating room. |
| | Second Annual Practice Management Conference for Anesthesiology Residents and Fellows |
| 1997 | Ready for the Real World, Chicago, IL What bioethics can do for you? Workshop on Practical Bioethics for the Anesthesiologist. |
| 1771 | American Society of Anesthesiologists |
| 1998 | Social capital |
| 1770 | Department of Anesthesiology, Rush-Presbyterian-St. Luke's Medical Center |
| 1998 | Ethical challenges for the practice of anesthesiology. |
| | Kentucky Society of Anesthesiologists Spring Meeting |
| 1998 | Panel on military anesthesia |
| | Society of Air Force Clinical Surgeons 45 th Annual Meeting |
| 1998 | The importance of modeling. |
| | Society of Air Force Clinical Surgeons 45 th Annual Meeting |
| 1998 | Grand Rounds. The business of anesthesiology is not just business: obligations to the |
| | patient and anesthesiology communities. |
| | Department of Anesthesiology and Critical Care, Children's Hospitalof Philadelphia, |
| 1998 | University of Pennsylvania Ethics in education. Innovation and challenges in anesthesiology education. |
| 1990 | Society for Education in Anesthesia, Fall Meeting |
| 1998 | Grand Rounds. Ethics in wartime medicine. |
| 1770 | Brooke Army Medical Center, Fort Sam Houston |
| 1998 | Clinical Forum on Ethics. |
| | American Society of Anesthesiologists Annual Meeting |
| 1999 | Ethical rules for humanitarian missions. |
| | Society of Air Force Clinical Surgeons 46 th Annual Meeting |
| 1999 | Ethical considerations in pediatric trauma. TraumaCare '99 Symposium |
| | International Trauma Anesthesia and Critical Care Society, Chicago |
| 1999 | Conflict and communication with patients. |
| 1000 | American Society of Anesthesiologists Annual Meeting |
| 1999 | Perioperative refusal of resuscitation. |
| 2000 | Department of Anesthesiology, University of Texas Health Science Center |
| 2000 | Perioperative refusal of resuscitation. Department of Anesthesiology, Hartford Hospital |
| 2000 | Perioperative refusal of resuscitation. |
| 2000 | New York Presbyterian Hospital and Weill Medical College at Cornell |
| 2000 | DNR in the OR. |
| 2000 | Harvard Medical School Anesthesia Review & Update |
| 2000 | Clinical Forum on Ethics. |
| | American Society of Anesthesiologists Annual Meeting |
| 2000 | The business of anesthesiology is not just business. |
| | Utah Society of Anesthesiologists Winter Meeting |
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| 2001 | Are we prepared for nuclear war? |
|------|--|
| | American Society of Anesthesiologists Annual Meeting |
| 2002 | The centrality of civility to professionalism. |
| | American Society of Anesthesiologists Annual Meeting |
| 2003 | Role of World War II in the development of anesthesiology as a medical profession. |
| | Anesthesia History Association 10 th Annual Spring Meeting |
| 2003 | Clinical Forum on Ethics. |
| | American Society of Anesthesiologists Annual Meeting |
| 2003 | The uncivil and unprofessional physician. |
| | American Society of Anesthesiologists Annual Meeting |
| 2003 | Perioperative DNR orders. |
| | American Society of Anesthesiologists Annual Meeting |
| 2003 | Obstetric anesthesia and analgesia before 1950. |
| •000 | American Society of Anesthesiologists Annual Meeting |
| 2003 | Social capital in the operating room. |
| 2002 | Society of Air Force Clinical Surgeons Annual Meeting, Anesthesia Section |
| 2003 | Plenary Session: Lt. Kornfield, World War II physician-anesthetist: why his story matters. |
| 2002 | Anesthesia History Association Spring Meeting |
| 2003 | Social Capital. |
| 2004 | SAUSHEC Anesthesiology Residency Program, San Antonio |
| 2004 | Social Capital New York Presbyterian Hospital and Weill Medical College at Cornell |
| 2004 | Ethical aspects of refusing transfusion therapy in minors. |
| 2004 | Practical Aspects of Pediatric Anesthesia |
| 2006 | Lethal Injection. |
| 2000 | American Society of Anesthesiologists Annual Meeting |
| 2006 | Social Capital. |
| 2000 | Department of Anesthesiology and Pain Medicine, St. Elizabeth's Medical Center |
| 2006 | Physician participation in capital punishment. |
| | Department of Anesthesiology and Perioperative Medicine, Mayo Clinic, Rochester |
| 2007 | PERCS - Simulation for Informed Consent. |
| | Department of Anesthesia and Critical Care, Massachusetts General Hospital |
| 2007 | Clinical Forum on Ethics. |
| | American Society of Anesthesiologists Annual Meeting |
| 2007 | What if Lord Nuffield had not found a Chair of Anesthesia? |
| | American Society of Anesthesiologists Annual Meeting |
| 2008 | Proposal for format for pediatric anesthesiology department. |
| | Department of Anesthesia, University of Iowa |
| 2008 | Primer in ethics. |
| | Society of Pediatric Anesthesia 22 nd Annual Meeting |
| 2008 | John Snow: Pump handles and infectious disease. |
| | American Society of Anesthesiologists Annual Meeting |
| 2008 | Putting it all together: A curriculum. |
| | Wood Library - Museum of Anesthesiology Forum on the History of Medicine. American |
| 2000 | Society of Anesthesiologists Annual Meeting |
| 2008 | World War Two: The crucible of "modern" anesthesiology. |
| | Roderick K. Calverley, M.D., Memorial Lecture. Anesthesia History Association Annual |
| | Dinner Meeting |

| 2009 | Donation after cardiac death. |
|------|---|
| | ASA Forum on Ethics. American Society of Anesthesiologists Annual Meeting |
| 2009 | Oh my God, she's pregnant! |
| | SPA/AAP Breakfast Panel |
| 2010 | Bedside medical ethics during natural disasters. |
| | Arkansas Children's Hospital, University of Arkansas |
| 2010 | Physician participation in capital punishment. |
| | Ogden Surgical Medical Society |
| 2010 | When is a kid an adult? – Ethics of assent and consent for adolescent regional anesthesia. |
| | Panel on Pediatric Anesthesia, American Society of Anesthesiologists Annual Meeting |
| 2010 | Ethical dilemmas with health care reform. |
| | Panel on Ethics, American Society of Anesthesiologists Annual Meeting |
| 2010 | Moderator and participant: Should physicians be permitted to participate in lethal injection. |
| | Panel on Professionalism: American Society of Anesthesiologists Annual Meeting |
| | Moderator: The Patrick Sim Forum on the History of Anesthesiology. |
| | American Society of Anesthesiologists Annual Meeting |
| 2011 | Moderator: The Patrick Sim Forum on the History of Anesthesiology. |
| | American Society of Anesthesiologists Annual Meeting |
| 2012 | Medical ethics. |
| | Department of Anesthesiology and Perioperative Medicine, University of Missouri School |
| | of Medicine |
| 2012 | Moderator: The Patrick Sim Forum on the History of Anesthesiology. |
| | American Society of Anesthesiologists Annual Meeting |
| 2013 | Moderator: The Patrick Sim Forum on the History of Anesthesiology. |
| | American Society of Anesthesiologists Annual Meeting |
| 2013 | Keynote speaker. Norman Kornfield and his relevance to modern day military medicine. |
| | Uniformed Services Society of Anesthesiologists Dining Out |
| 2014 | Moderator: The Patrick Sim Forum on the History of Anesthesiology |
| | American Society of Anesthesiologists Annual Meeting |
| 2015 | Moderator: The Patrick Sim Forum on the History of Anesthesiology |
| | American Society of Anesthesiologists Annual Meeting |
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International

| 1999 | Physician aid-in-dying. |
|-------|---|
| | Austrian International Congress on Anesthesia, Vienna, Austria |
| 2001 | Things never change. (Invited, not presented) |
| | 5 th International Symposium on the History of Anesthesia |
| | Santiago, Spain |
| 2008 | Plenary Symposium "The future of anesthesia practice." |
| | Annual Meeting of the Canadian Anesthesiologists' Society, Halifax, Canada |
| 2008 | World War Two: The crucible of "modern" anesthesiology. |
| | Roderick K. Calverley, M.D., Memorial Lecture. Anesthesia History Association Annual |
| | Dinner Meeting |
| 20011 | Ethics of organ transplantation. 58 th Annual Meeting of the Japanese Society of |
| | Anesthesiologists |
| 2012 | Regional anesthesia and war. |
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| | 15 th WFSA World Congress Anesthesiologists, Buenos Aires, Argentina |
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| 2013 | ABA board certification. |
| | 8 th International Society History of Anesthesia Meeting, Sidney, Australia |
| 2013 | Informed consent. |
| | 20 th Panhellenic Congress of Anesthesia, Athens, Greece |
| 2013 | DNR in the operating room. |
| | 20 th Panhellenic Congress of Anesthesia, Athens, Greece |

Current Licensure and Certification

| 1993- | Massachusetts Board of Medicine Licensure |
|-------|---|
| 1994 | Diplomate of the American Board of Anesthesiology |
| 2005 | Voluntary Recertification in Anesthesiology (through 12/31/2015) |
| 2013 | Pediatric Anesthesiology, Diplomate of the American Board of Anesthesiology |

Report of Scholarship

Peer reviewed publications in print or other media

- 1. Truog RD, Waisel DB. Amnesia instead of anesthesia: not always a question of consent. J Clin Ethics 1994;5:153-5.
- 2. Waisel DB, Fackler JC, Brunner JX, Kohane I. PEFIOS: an expert closed-loop oxygenation algorithm. Medinfo 1995;8Pt2:1132-6.
- 3. Waisel DB, Truog RD. The cardiopulmonary resuscitation-not-indicated order: futility revisited. Ann Intern Med 1995;122:304-8.
- 4. Waisel DB, Truog RD. The benefits of the explanation of the risks of anesthesia in the day surgery patient. J Clin Anesth 1995;7:200-4.
- 5. Liang BA, Truog RD, Waisel DB. What needs to be said? Informed consent in the context of spinal anesthesia. J Clin Anesth 1996;8:525-7.
- 6. Waisel DB, Truog RD. An introduction to ethics. Anesthesiology 1997;87:411-7.
- 7. Waisel DB, Truog RD. The end-of-life sequence. Anesthesiology 1997;87:676-86.
- 8. Waisel DB, Truog RD. Informed consent. Anesthesiology 1997;87:968-78.

- 9. Waisel DB, Truog RD. How an anesthesiologist can use the ethics consultation service. Anesthesiology 1997;87:1231-8.
- 10. Medell RJ, Waisel DB, Eskuri SA, Calicott RW. Field block for cranial surgery in World War II. Mil Med 1998;163:80-3.
- 11. Affleck PJ, Waisel DB, Cusick JM, Van Decar T. Recall of risks following labor epidural analgesia. J Clin Anesth 1998;10:111-4.
- 12. Scheu KL, Waisel DB. Regional anesthesia equipment checkout recommendations: A case report and discussion. J Clin Anesth 1998;10:502-5.
- 13. Truog RD, Waisel DB, Burns JP: DNR in the OR: A goal-directed approach. Anesthesiology 1999;90:289-95.
- 14. Waisel DB. Nonpatient care obligations of anesthesiologists. Anesthesiology 1999;91:1152-8.
- 15. Waisel DB, Vanscoy SEG, Tice LH, Bulger K, Schmelz J, Perucca P. Activities of an ethics consultation service in a tertiary military medical center. Mil Med 2000;165:528-32.
- 16. Waisel DB. The hazards of "hanging crepe" or stating overly pessimistic prognoses. J Clin Ethics 2000;11(2):171-4.
- 17. Waisel DB. The role of World War II and the European Theatre of Operations in the development of anesthesiology as a physician specialty in the USA. Anesthesiology 2001;94:907-14.
- 18. Truog RD, Waisel DB. Do-not-resuscitate orders: from the ward to the operating room; from procedures to goals. Int Anesthesiol Clin 2001;39(3):53-66.
- 19. Waisel DB, Burns JP, Johnson JA, Hardart GE, Truog RD. Guidelines for perioperative donot-resuscitate policies. J Clin Anesth 2002;14:467-73.
- 20. Waisel DB. Norman's War: Norman B. Kornfield, MD, World War II physician-anesthetist. Anesthesiology 2003;98:995-1003.
- 21. Elder J, Waisel DB. Case report of the one-armed anesthesiology resident. J Clin Anesth 2004;16:445-8.
- 22. Waisel DB. Moral permissibility as a guide for decision making about conjoined twins. Anesth Analg 2005;101:41-3.
- 23. Waisel DB. Developing social capital in the operating room: the use of population-based techniques. Anesthesiology 2005;103:1305-10.
- Wright L, Waisel DB, Bacon DR. The Anlet: Anesthesiology's response to the needs of the Armed Forces in World War II. Anesthesiology 2006;104:179-82.

- 25. Waisel DB. Physician participation in capital punishment. Mayo Clin Proc 2007;82:1073-82.
- 26. Waisel DB, Truog RD. A continuum for using placebo interventions in regional anesthesia and analgesia studies. Clin Pharmacol Ther 2008;84:163-5.
- 27. Gawande A, Denno DW, Truog RD, Waisel D. Physicians and execution--highlights from a discussion of lethal injection. N Engl J Med 2008;358:448-51.
- 28. Waisel DB, Lamiani G, Sandroc N, Pascucci R, Truog RD, Meyer EC. Anesthesiology Trainees Face Ethical, Practical and Relational Challenges in Obtaining Informed Consent. Anesthesiology 2009;110:480-6.
- 29. Waisel DB, Simon R, Truog RD, Baboolal H, Raemer DB. Anesthesiologist Management of Perioperative Do-Not-Resuscitate Orders: A Simulation-Based Experiment. Simulation in Healthcare 2009;4:70-6.
- 30. Waisel DB. Moral responsibility to attain thorough pediatric drug labeling. Peaediatr Anaesth 2009;19:989-93.
- 31. Waisel DB. Let the patient drive the informed consent process: ignore legal requirements. Anesth Analg 2011;113:13-5.
- 32. Waisel DB. Vulnerable populations in healthcare. Curr Opin Anaesthesiol 2013 Apr;26(2):186-92.
- 33. Waisel DB. Thoughts on the Bulletin. Bull Anesth Hist. 2013:31(1):1
- 34. Waisel DB. Unrecognized Barriers to Perioperative Limitations on Potentially Life-Sustaining Medical Treatment Journal of Clinical Anesthesia. J Clin Anesth 2014;26:171-3.
- 35. Waisel DB. Revocation of board certification for legally permitted activities. Mayo Clin Proc 2014;89:869-72.
- 36. Edwards ML, Waisel DB. 49 Mathoura Road Geoffrey Kaye's Letters to Paul M. Wood, 1939–1955. Anesthesiology 2014;121(6):11150-7.
- 37. Waisel DB. Welcome to the Journal of Anesthesia History. J Anesth Hist. 2015;1(1):1. DOI: http://dx.doi.org/10.1016/j.janh.2014.11.001
- 38. Waisel DB, Mancuos TJ, Boretsky R. Pediatric Research, Risk, and Paravertebral Blocks. Anesth Analg. 2015 May;120(5):987-9. doi: 10.1213/ANE .0000000000000638
- 39. Waisel DB. A Select History of the Professional Standards of The American Board of Anesthesiology. Proceedings of the 8th International Symposium on the History of Anaesthesia.
- 40. Edwards ML, Waisel DB. 49 Mathoura Road: Geoffrey Kaye's Center of Excellence for the Exhibit page 81 of 97.

Australian Society of Anaesthetists. Anesthesiology. 2016;124:122-9.

Non-peer reviewed scientific or medical publications/materials in print or other media

- 1. Waisel DB. Should medical professionals participate in executions. The National Association of Defense Lawyers Champion Magazine. June 2010, p 38.
- 2. Waisel DB, Litton P. Why the lethal injection drug debated by the Supreme Court today is unconstitutional. New Republic. April 29, 2016.

Professional educational materials or reports, in print or other media

- 1. Waisel DB. The physician in the arms race. In: Newell JD, Gabrielson IW. *Medicine Looks at the Humanities*. Maryland: United Press of America; 1987. p. 127-9.
- 2. Waisel DB. Euthanasia. Ethical Issues in Anesthesia, *Advances in Anesthesia*. St. Louis: Mosby-Year Book; 1997. p. 250-3.
- 3. Waisel DB, Van Norman G. ASA 1997 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1997.
- 4. Waisel DB. Introduction to ethics. In: Waisel DB, Van Norman G. ASA 1997 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1997.
- 5. Merrill DG, Waisel DB. Physician-assisted suicide: Con/Pro. American Society of Anesthesiologists Newsletter 1998;62(3):5-8.
- 6. Waisel DB, Van Norman G. ASA 1998 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1998.
- 7. Waisel DB, Van Norman D, Fine P. Hospice Care: Living all the days of your life: An interview with Perry Fine, MD. In: Waisel DB, Van Norman G, editors. ASA 1998 Syllabus on Ethics. Park Ridge, IL: American Society of Anesthesiologists; 1998.
- 8. Waisel DB. Perioperative DNR orders: new options, greater flexibility. American Society of Anesthesiologists Newsletter, 1999;63(4):5-8.
- 9. Waisel DB, Jennings JE. Informed consent in anesthesiology. In: Bready LL, Mullins RM, Noorily SH, Smith RB, editors. Decision Making in Anesthesiology, 3rd ed. St. Louis: Mosby-Year Book; 1999. p. 54-5.

- 10. Jennings JE, Waisel DB. Do-not-resuscitate in the operating room. In: Bready LL, Mullins RM, Noorily SH, Smith RB, editors. Decision-Making in Anesthesiology, 3rd ed. St. Louis: Mosby-Year Book; 1999. p. 56-57.
- 11. Waisel DB. Perioperative Do-not-resuscitate orders. Current Opinion in Anesthesiology 2000; 13:191-4.
- 12. Waisel DB, Truog RD, Todres ID. Ethical issues in pediatric anesthesiology. In: Cote CJ, Ryan JF, Todres ID, Goudsouzian NG, editors. A Practice of Anesthesia for Infants and Children, 3rd ed. Philadelphia: W.B. Saunders; 2001. p. 68-78.
- 13. Waisel DB, Truog RD. Informed consent for the patient with an existing DNR order. American Society of Anesthesiologists Newsletter 2001;65(3):13-4.
- 14. Waisel DB. Getting informed consent: an anesthesiologist's perspective. Inspirations: The Anesthesia Residents' Quarterly 2001;4(1):1-7.
- 15. Waisel DB. Could the attending be wrong? Inspirations: The Anesthesia Residents' Quarterly, 2001;4(3):12-6.
- 16. Waisel DB. Ethical issues in pain management and end-of-life care for the AIDS patient. In: Nedeljkovic S. Pain Management of HIV/AIDS Patients. Woburn: Butterworth Heinemann; 2002. p. 175-86.
- 17. Waisel DB. Ethical and legal issues in pediatric care. In: Yemen TA. Pediatric Anesthesia Handbook. New York: McGraw-Hill; 2002. p. 13-25.
- 18. Waisel DB, Medical professionalism: is it necessary or too arbitrary? American Society of Anesthesiologists Newsletter 2002;66(7).
- 19. Waisel DB. Perioperative DNR orders. American Society of Anesthesiologists Newsletter 2002;66(10).
- 20. Waisel D, Jackson S, Fine P. Should do-not-resuscitate orders be suspended for surgical cases? Curr Opin Anaesthesiol. 2003;16:209-13.
- 21. Waisel DB, Truog RD. Medical ethics and anaesthesia, In: Healy TEJ, Cohen PJ, editors. Wylie and Churchill-Davidson's A Practice of Anaesthesia, 7th ed. London: Arnold; 2003. p. 1341-52.
- 22. Van Norman G, Jackson SH, Waisel D. Informed consent: ethical implications in clinical practice. Curr Opin Anaesthesiol. 2004;17:177-81.
- 23. Truog RD, Waisel DB, Burns JP. Do-not-resuscitate orders in the surgical setting (editorial). Lancet 2005;365:733-5.
- 24. Waisel DB, Truog RD. Ethical and legal aspects, In: Miller RD. Anesthesia, 6th ed.

- Philadelphia: Elsevier Churchill Livingstone; 2005. p. 3175-98.
- 25. Waisel DB. Ethical and legal considerations in pediatric anesthesia. In: Holzman RS, Mancuso TJ, Polaner DM, eds. A Practical Approach to Pediatric Anesthesia. Philadelphia: Lippincott Williams & Williams; 2008. p. 71-8.
- Waisel DB, Truog RD, Todres ID. Ethical issues in pediatric anesthesiology.
 In: Cote CJ, Lerman J, Todres ID, eds. A Practice of Anesthesia for Infants and Children, 4th ed. Philadelphia: W.B. Saunders; 2009. p. 71-88.
- 27. Waisel DB. Ethical issues in critical Care. In: Gabrielli A, Layon AJ, Yu M, editors. Civetta, Taylor, Kirby's Critical Care, 4th ed. Philadelphia: Lippincott Williams & Wilkins; 2009.
- 28. Clendenin D, Waisel DB. Informed consent and the pediatric patient. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 33-8
- 29. Quaine JG, Waisel DB. Ethical use of restraints. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 61-3.
- 30. McClain CD, Waisel DB. Triage and treatment of wounded during armed conflict. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 275-9.
- 31. Waisel DB. Physician facilitation of torture and coercive interrogation. In: Van Norman GA, Jackson S, Rosenbaum SH, Palmer SK. New York: Cambridge University Press; 2011. p. 280-4.
- 32. Waisel DB. Ethics and conflict of interest in anesthesia practice. In: Longnecker D, Brown DL, Newman MF, Zapol W. Anesthesiology, 2nd ed. 2012. P 45-50,
- 33. Waisel DB. Editor. Bulletin of Anesthesia History. 2012:30 (1).
- 34. Waisel DB. Editor. Bulletin of Anesthesia History. 2012:30(2).
- 35. Waisel DB. Ethical issues in pediatric anesthesiology. In: Cote CJ, et al, eds. A Practice of Anes for Infants and Children, 5th ed. Philadelphia: W.B. Saunders. 2012. p. 64-76.
- 36. Waisel DB. Ethical issues in pediatric anesthesiology. In: Cote CJ, et al, eds. A Practice of Anes for Infants and Children, 5th ed. Philadelphia: W.B. Saunders. 2013. p. 64-76.
- 37. Waisel DB. Editor. Bulletin of Anesthesia History. 2013:31(1).
- 38. Waisel DB. Editor. Bulletin of Anesthesia History. 2013:31(2).
- 39. Waisel DB. Editor. Bulletin of Anesthesia History. 2014:32(1).
- 40. Waisel DB. Editor. J Anesth Hist. 2015:1(1).

- 41. Waisel DB. Editor. J Anesth Hist. 2015:1(2).
- 42. Waisel DB. Editor. J Anesth Hist. 2015:1(3).
- 43. Waisel DB. Editor. J Anesth Hist. 2015:1(4).
- 44. Waisel DB. Legal Aspects of Anesthesia Care in America, In: Miller RD. Miller's Anesthesia, 8th ed. Philadelphia: Elsevier Churchill Livingstone; 2015. p. 251-267.
- 45. Zaleski KL, Waisel DB Withholding information from an anxiety-prone patient? AMA J Ethics. 2015 Mar 1;17(3):209-14. doi: 10.1001/journalofethics.2015.17.3.ecas2-150
- 46. Waisel DB. Disagreements between medical specialty boards and their diplomates. AMA J Ethics. 2015 Mar 1;17(3):193-8. doi: 10.1001/journalofethics.2015.17.3.spec1-1503.
- 47. Waisel DB.Introduction: Unfamiliar Ethical Issues. Int Anesthesiol Clin. 2015 Summer;53(3):vi 10.1097/AIA.00000000000055. PMID: 26057909.
- 48. Waisel DB. Challenges in the LGBTQI+ Community. Int Anesthesiol Clin. 2015 Summer;53(3) 10.1097/AIA.00000000000064. No abstract available. PMID: 26057902.
- 49. Waisel DB. Guest Editor. Unfamiliar Ethical Issues. Int Anesthesiol Clin. 2015 Summer; 53(3).
- 50. Waisel DB. Editor. J Anesth Hist. 2016:2(1).
- 51. Waisel DB. Editor. J Anesth Hist. 2016:2(2).
- 52. Waisel DB. Editor. J Anesth Hist. 2016:2(3).

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EXHIBIT H

County of San Jacinto State of Texas

AFFIDAVIT OF LILIANE STICHER

My name is Liliane Sticher, and I reside in Marly, Switzerland. I'm currently visiting Texas. I am over 18 years of age and of sound mind. I swear under the penalties of perjury that this statement is true and correct to the best of my knowledge.

- 1. I received a Ph.D. in Biology from the University of Geneva, Switzerland.
- 2. I corresponded with Texas death row inmate William Rayford ("William") for approximately 7 months.
- 3. On the evening of January 30, 2018, I witnessed William's execution.
- 4. After William pronounced his last words, William laid down still. I saw the tubing move slightly, indicating liquid going through. William began to seem to fall asleep, although he hadn't closed his eyes. At one point he began to snore and I thought that it was going to proceed as I had been told it would.
- 5. Then, William raised the upper part of his body to about 30 degrees. He was shaking and looked at me as if he wanted to say something, as if in distress, as if asking for help. He was shaking. The upper part of his body was shaking. He slowly went back down on the table, still shaking.
- 6. At one point he began to snore but then his eyes opened completely again.
- 7. Several times I felt that now he was going to really fall asleep as we were told would happen, but then he would start breathing heavier again. He didn't close his eyes while he was breathing heavily and on his back.
- 8. The shaking occurred more than once, but I am not sure how many times it happened. Several times I thought that William would wake up completely again because of the way he was breathing, at times gently and then heavier again. It was not like going to sleep.
- 9. At one point I noticed a quite-large bubble of air traveling in the tubing going into William's arm. I remember being surprised because I know that air in veins causes gas embolisms.
- 10. I kept thinking that William was gone but then would hear him breath again. Then, the doctor came in as we had been told he would. I couldn't see precisely what he did because he had his back in front of us. I saw that he used his stethoscope and placed it on William's chest at several locations but did other things too. Then, he said 8:48 and I knew that William was dead.

| Respectfully | submitted, |
|--------------|------------|
| | |

Liliane Sticher

SUBSCRIBED AND SWORN to before me on this _____ day of _February___ 20_/8__.

Notary Public

290 US Noy 196 W. Living Ston TE 77381 Address

| KENNETH HIGHTOWER |
|---|
| Notary Public State of Texas My Commission# 126860244 My Comm. Exp. Apr. 06, 2021 |

My Commission Expires: 4/6/21

EXHIBIT I

County of Liberty State of Texas

AFFIDAVIT OF DANIELLE ALLEN

My name is Danielle Allen, and I reside in Cleveland, Texas. I am over 18 years of age and of sound mind. I swear under the penalties of perjury that this statement is true and correct to the best of my knowledge.

- 1. I attended the execution of William Rayford on the evening of January 30, 2018. I was one of Mr. Rayford's approved witnesses and was in the viewing room during the execution.
- 2. When they started to administer the drugs to Mr. Rayford, his body jerked up, and he faced his friends in the witness area. He tried to say a few words, but they were slurred and I couldn't understand them.
- 3. When the drugs entered Mr. Rayford, his eyelids twitched, and then his head jerked back into the pillow.
- 4. After Mr. Rayford's head jerked into the pillow a couple of times like this, he lifted his head again. This time his face was twisted into a grimace. His eyes were squinted, and his face was tensed. It's hard to describe but Mr. Rayford was clearly in severe pain.
- 5. Then, his head jerked back into the pillow again, and his body continued to shake.
- 6. Mr. Rayford breathed heavily and unevenly for a while until we could no longer hear him breathing.
- 7. After a long time, a doctor checked Mr. Rayford's vitals and pronounced him dead.

Respectfully submitted,

Danielle Allen

SUBSCRIBED AND SWORN to before me on this day of February 20 18.

Notary Public

SHARLENE NOVAK
Notary Public, State of Texas
Comm. Expires: 11-11-2018

My Commission Expires: 11-11-2018

EXHIBIT J

County of Harris State of Texas

AFFIDAVIT OF K. KNOX NUNNALLY

My name is K. Knox Nunnally, and I reside in Houston, Texas. I am over 18 years of age and of sound mind. I swear under the penalties of perjury that this statement is true and correct to the best of my knowledge.

- 1. I was Anthony Shore's legal counsel. I knew Mr. Shore for about four years. I visited with him personally at the TDCJ Polunsky Unit multiple times over those four years. These observations are based on my extensive knowledge of him.
- 2. I attended the execution of Anthony Shore on the evening of January 18, 2018. I was one of Mr. Shore's approved witnesses and was in the viewing room during the execution.
- 3. I was the third person to enter the viewing room and took a position close to the glass separating the viewers from the execution chamber. All three of Mr. Shore's witnesses were next to the glass with a clear, unobstructed view of the execution.
- 4. Soon after Mr. Shore said his final words, he had a visible and audible reaction to the lethal-injection drugs. He said, in a stressed voice, "Ohh weeee, I can feel that it does burn. Burning!"
- 5. After he said that he was burning, he shut his eyes.
- 6. I feel his words were true because his voice got progressively stressed and louder.
- 7. After he said that he was burning, he went quiet. After about 5-7 minutes, the doctor came and checked Mr. Shore's vitals before pronouncing him deceased at 6:28 p.m.

8. As the chaplain walked me outside the execution chamber, he said, "That's the first time I've heard anyone say they are burning."

K. Knox Nunnally

SWORN TO AND SUBSCRIBED before me, the undersigned authority, on this 1^{st} day of February, 2018.

PATRICIA S. FAULK

Notary Public, State of Texas

Comm. Expires 09-07-2019

Notary ID 008674598

Notary Public in and for the

State of Texas

EXHIBIT K

County of Polk State of Texas

AFFIDAVIT OF NISKI PAREDES

My name is Niski Paredes, and I reside in Livingston, Texas. I am over 18 years of age and of sound mind. I swear under the penalties of perjury that this statement is true and correct to the best of my knowledge.

- 1. I was Anthony Shore's spiritual adviser. The Universal Life Church ordained me on May 4, 2016. These observations are based on my extensive knowledge of Mr. Shore, his manner, voice, and expressions.
- 2. I attended the execution of Anthony Shore on the evening of January 18, 2018. I was one of Mr. Shore's approved witnesses and was in the viewing room during the execution.
- 3. I was the first person to enter the viewing room and took the seat closest to the glass separating the viewers from the execution chamber. The seat was the furthest left of the room.
- 4. I did not sit down during the execution. Instead, I stood and focused my attention on Mr. Shore.
- 5. About two minutes after he said his final words, Mr. Shore's body started to tremble.
- 6. He then said, in a stressed voice, "Ohh weeee, I can feel that it does burn. Burning!" As he said this his voice became progressively louder and more agitated.
- 7. After that he shut his eyes and had a desperate look on his face. His chin and lips quivered. The veins on the side of his head protruded and appeared to swell. Mr. Shore appeared to be struggling to breathe.
- 8. He then went quiet. I noticed the Warden would look over at him, then shut his eyes before looking at Mr. Shore again. The Warden did this a couple of times.
- 9. About 6-7 minutes after Mr. Shore went still, the doctor came and checked his vitals before pronouncing him dead at 6:28 pm.
- 10. As the chaplain walked me outside the execution chamber, he said, "That's the first time I've heard anyone say they are burning."

Respectfully submitted,

Wiski Paredes

Niski Paredes

SUBSCRIBED AND SWORN to before me on this

I day of fe Grua

HENRIETTA C. NORMAN Notary Public, State of Texas Notary ID # 12539811-2 Comm. Exp.: 08-15-2021

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Notary Public

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Address

My Commission Expires:

Exhibit page 97 of 97.